DOCTOR OF PHILOSOPHY

Exploring prostate cancer survivors' self-management behaviours and social supportive experiences using questionnaires and electronic behavioural diaries:

does social support buffer the relationship between coping and health-related quality of life?

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Award date:
2013

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2013

University of Dundee

Exploring prostate cancer survivors' self-management behaviours and social supportive experiences using questionnaires and electronic behavioural diaries: Does social support buffer the relationship between coping and health-related quality of life?

Thesis submitted for the Degree of Doctor of Philosophy

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April 2013

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Index of terms

AS	Active Surveillance
BNI	British Nursing Index
BSSS	Berlin Social Support Scale
BT	Brachytherapy
DRE	Digital Rectal Examination
EORTC	European Organisation for Research and Treatment of Cancer
FACT	Functional Assessment of Cancer Therapy
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health-Related Quality of Life
HT	Hormone Therapy
LRP	Laparoscopic Radical Prostatectomy
MAC Scale	Mental Adjustment to Cancer Scale
NA	Negative Affect
PA	Positive Affect
PC	Prostate Cancer
PSA	Prostate Specific Antigen
PRISMA	Preferred Reporting of Items for Systematic Reviews and Meta-Analyses
PSS	Perceived Stress Scale
RP	Radical Prostatectomy
RT	Radiotherapy
SF-36	Short Form (36) Health Survey
TRUS	Trans-Rectal Ultrasound
TNM	Tumour, Node and Metastases Staging System
UK	United Kingdom

Declaration

Candidate's Declaration

(i) I, Catherine Isobel Elizabeth Paterson, hereby certify that this thesis, which is approximately 80,000 words in length, has been written by me, that is the record of work carried out by me, and that it has not been submitted in any previous applications for a higher degree.

Date……. Candidate's Signature……

Supervisors' Declaration

(ii) We hereby certify that the candidate has fulfilled the conditions of the relevant Ordinance, and Regulations of the University of Dundee, and that as such the candidate is eligible to submit the following thesis in application for the degree of Doctor of Philosophy.

Date……. Supervisor's Signature……

Date……. Supervisor's Signature……

Date……. Supervisor's Signature……

Acknowledgments

Completing this thesis, a product of several years' work, I feel deeply indebted to a number of special people who have greatly inspired and supported me during my Ph.D. education. It is with pleasure, to thank the many people who made this thesis possible.

Firstly, I would like to express my sincere gratitude to the College of Medicine, Dentistry and Nursing for awarding me the Ph.D. Scholarship, which made this research possible. A further acknowledgement must go to the School of Nursing and Midwifery, for allowing me to grow in my love with nursing.

I am very grateful to my Ph.D. supervisors: Prof. Martyn Jones, Dr. Janice Rattray and Prof. Billy Lauder in supporting my intellectual growth. In particular, I would like to thank my supervisors for their generous help, and comments, which enabled me to reflect upon my work and develop my academic ability.

I would also like to thank Mr Christopher Goodman (Urology Clinical Lead), Mrs Allison Robertson, Mr Ghulam Nabi, and all of the NHS Tayside Urology Team for your support of my research, and of me. I would also like to say "a very special thank you" to all of the participants who made this research possible.

I would also like to thank the members of my research steering group for their expert guidance. A further word of thanks must go to Andrew Howe (Head of Computing & Media Services) for his help in developing my Access database. I am also very grateful to Aileen Ireland for sharing her expertise of English literature with me.

God was a major source of strength to me and I want to acknowledge Him. I would like to thank my friends and family. In particular, I owe hugely to my dear mum, Maria Woolfries, for her permanent love and confidence in me who encouraged me to go ahead in my Ph.D. and in my nursing career. Specifically, I want to appreciate her for taking very special care of my young children when I worked on my Ph.D. For my sweet daughter, Faith, and strong boy, Ethan, I am eternally grateful for keeping me focused on the things that are the most important life, them. Finally, but definitely not the least, I express my gratitude to my husband, Nathan. I am so appreciative for his constant love, understanding, unwavering patience, and for bearing the pressures, both from my Ph.D. and our young family during my study. I dedicate this thesis to him.

Summary

Background: Prostate cancer is now the most common type of cancer in men in the UK. Physical effects of treatments have been well documented; however, the extent to which psycho-social factors may impact upon health-related quality of life (HRQoL) is limited. Little is known about the self-management behaviours of men affected by prostate cancer or how they cope with prostate cancer. Men living with and beyond prostate cancer have reported a lack of support in their pursuit to cope with the physical and psychological sequelae. Social support may help men with self-management, but may also buffer the relationship between coping and HRQoL. Most healthcare research has been conducted *between individuals* and is limited to aggregate group level effects, and has overlooked the importance of *within-person* experience and change over time. Any future theoretically driven intervention study should be supported empirically at the level it is intended: "the individual man".

Aim: To assess the mechanism effect between the relationship that links coping and social support to HRQoL in a sample of men affected by prostate cancer using between individuals and within individual methodological approaches. In addition, this thesis aimed to identify the actual self-management behaviours and social supportive experiences of men over the cancer journey, between and within individuals over time.

Methods: A quantitative approach consisted of a prospective, longitudinal survey and single-case electronic diary data. Clinical, demographic and survey data were collected at baseline (before treatment) and at 6 months follow-up. A sub-sample of n=12 participants completed an electronic behavioural diary for 1 month. Men completed the electronic behavioural diary in the month following their treatment. The duration, timing and design of the behavioural diary were guided by methodological considerations, service users and clinicians' comments.

Findings: The prospective longitudinal survey identified that baseline perceived social support was the most important social support construct that predicted HRQoL (β=0.266, p=0.021) and depression (β=0.243, p=0.029) at 6 months and explained approximately 30% of the variance of the dependent variables. Moderation and

mediation effects were not identified from the prospective longitudinal findings. Testing theoretical models “within-individuals” over time demonstrated different results for main, moderating and mediating pathways that linked coping and social support to emotional outcome. Men performed a number of self-management behaviours for urinary, bowel and sexual dysfunction, but often with little relief.

Discussion/Relevance: Real time data collection moves far beyond traditional retrospective evaluations, enabling a much clearer understanding of the individual patient experience over time. The results from the series of single-case studies have demonstrated the one size does not fit all. The findings from the prospective longitudinal study and the 11 single-case studies suggest that men may benefit from a supported self-management intervention study tailored to the “individual’s needs” of prostate cancer survivors.

Overview to this thesis

Prostate cancer is a specific type of cancer that can only affect males. The prostate is a gland, and forms part of the male reproductive system. The prostate gland is usually the size and shape of a walnut and it is located underneath the bladder and surrounds the urethra. Prostate cancer and its treatments have the potential to reduce health-related quality of life (HRQoL) for men living with and beyond prostate cancer. A growing number of studies have measured HRQoL and, as yet, no literature review has been conducted to identify the predictor variables of HRQoL or has detailed how HRQoL changes over time in this patient group. Chapter 1 presents a structured review of the empirical evidence that details the predictor variables of HRQoL and identifies how HRQoL changed over time for men affected by prostate cancer. The findings from this review identified that, despite the proliferation of HRQoL literature in recent years, little is known about the influence of the relationship between social support and coping on HRQoL, or the self-management behaviours of prostate cancer survivors. To ensure that the Ph.D. research questions were developed on the best available evidence it was necessary to conduct two further structured reviews of the empirical evidence.

Chapter 2 presents a structured review of the empirical evidence that aimed to identify which types of social support has been found to influence HRQoL and details the mechanism effect that links coping and social support to HRQoL in men with prostate cancer. The findings from this review demonstrated that few prospective longitudinal research designs have been implemented in this field to evaluate changes in social support provision. It seems likely that the types of social support needs will change throughout the cancer trajectory. Additional work is needed to assess how social supportive experiences change over time and this could be achieved through a prospective longitudinal design (to assess aggregate group effects) and case-based time series designs (to assess within-person change over time). Evaluating average group level effects and within-person design over time is an innovative approach which may expand and refine the propositions of social support theory.

A suitable theoretical framework to advance research in this area is the stress buffering model because it links social support and coping to HRQoL. Few studies have tested this theoretical framework in men affected by prostate cancer. The stress buffering model enabled the mechanism effect (main/moderation/mediation) of social support to be explored with coping and health-related outcomes for men affected by this disease. The development of our understanding of the mechanism effect that links coping and social support to HRQoL will facilitate the development of appropriately targeted interventions that are theoretically driven. Not only has social support been found to influence HRQoL but it may help men in their pursuit to self-manage.

Self-management for people affected by cancer is increasingly being recognised as a fundamental component of effective management of cancer care as a long-term condition. Men are keen to engage as active partners in the management of their condition but men have voiced a number of unmet support needs that make effective self-management problematic. Chapter 3 presents the third structured review of the empirical evidence that aimed to identify the self-management behaviours performed by men affected by prostate cancer and to establish whether self-management behaviours have been found to change over time. The findings from this chapter demonstrated that very little research has assessed self-management behaviours for prostate cancer survivors. There were five papers included in this review and this underscores that this field is under-developed. Additional research is urgently needed to establish the self-management behaviours of men within different clinical characteristics and level of social support. Developing this evidence base is very important because of the number of unmet support needs of these men, and the recent political drive for individuals to self-manage.

In summary, chapters 1, 2 and 3 are structured reviews of the empirical evidence that were conducted to add quality and rigour in developing the researcher's research questions. The findings from these reviews identified that men affected by prostate cancer may experience profound physical and psychological sequelae. Little is known about how men cope with the aftermath problems associated with this disease, the self-management behaviours that men use, or the relationship between coping and social support in relation to HRQoL. Based upon the results of the

literature review in chapter 2, a suitable theoretical framework to assess the influence of the relationship between coping and social support on HRQoL is the stress buffering model. This theoretical model was selected because it enabled main/moderation/mediation effects of social support and coping on HRQoL to be tested, and because very little research has tested the propositions of social support theory in men affected by prostate cancer. Developing an understanding of the influence of social support on HRQoL was very important because of the unmet support needs of these men.

Most healthcare research has been conducted to test aggregate group level effects and therefore, is restricted to hypothetical averages. Such approaches overlook the importance of *within-person* experience and change over time. Any future theoretically driven intervention study should be supported empirically at the level it is intended; *the individual man*. Therefore, the aim of this Ph.D. study was to test the stress buffering model between and within individuals over time and to assess the self-management behaviours and the social supportive experiences.

Chapter 4 identifies the research questions that addressed the aim of this Ph.D. study. This chapter (4) opens with a critical introduction into the chosen methodology. A quantitative approach consisted of a prospective longitudinal survey and 12 ecological momentary assessment (EMA) adapted/N-of-1 studies which were appropriate to address the overall study aim, and to answer the research questions. Participants were asked to complete a battery of questionnaires at baseline and 6 months follow-up. A sub-sample n=12 completed a daily electronic diary for a total duration of one month. The duration, timing and design of the EMA adapted/N-of-1 were guided by the literature and expert comment from the research steering group.

This quantitative approach enabled the theoretical model to be tested between individuals and within-individuals over time to advance understanding of the propositions of social support theory, but uniquely positioned the individual man at the centre of the research. This design enabled refinement of the propositions of social support theory. The design and methods chosen in this Ph.D. captured insights into, and quantifiable data on, men's social support and the self-management behaviours over the course of the cancer journey.

Chapter 5 presents the findings from the prospective longitudinal study and chapter 6 presents the findings from the case series of 12 electronic behavioural diaries. The clinical implications from the findings of this Ph.D. are discussed, and future directions for additional research are identified, in chapter 7.

1: Health-related quality of life and prostate cancer

1.1: Abstract

Background

Prostate cancer and its treatments have the potential to reduce health-related quality of life (HRQoL) for men living with and beyond prostate cancer. A growing number of studies have measured HRQoL and there is a pressing need to take stock of the existing evidence to identify predictors of HRQoL, and how HRQoL changes over time in this patient group. It is anticipated that knowledge in this area will drive attempts to understand the predictors of HRQoL and inform future research aimed to improve HRQoL.

Aim

To critically evaluate the empirical evidence that has identified the predictor variables of HRQoL and assessed changes in HRQoL over time for prostate cancer survivors.

Methods

A structured review of empirical literature published between 2005 and 2012 was included. Databases searched included: DARE, CDSR, Medline, CINAHL, PsycINFO, and ASSIA. Research studies which identified predictor variables of HRQoL or assessed changes in HRQoL over time were included.

Results

104 publications were reviewed. 53 studies identified predictor variables of HRQoL and 77 studies identified changes in HRQoL over time. Demographic (age, ethnicity, marital status, education), clinical variables (cancer stage, Gleason score, co-morbidity, treatments and prostate-specific antigen [PSA]) and psycho-social variables (coping, self-efficacy, perceived stress, coping, depression and social support) have been identified as predictors of HRQoL. Very few studies (six) investigated the influence of psycho-social variables on HRQoL. Prospective longitudinal data identified that men can experience reduced general HRQoL in the months following treatment, but prostate cancer-specific HRQoL can be negatively affected for many years after treatment.

Conclusion

Despite the proliferation of HRQoL literature in recent years, little is known about the influence of the relationship between social support and coping on HRQoL or the self-management behaviours of prostate cancer survivors. There is a pressing need to address this knowledge deficit to improve patient-reported outcomes. Moreover, developing an evidence base for self-management is a key feature of health care policy in the UK.

1.2: Introduction

Prostate cancer is now the most prevalent type of cancer in men in the United Kingdom (UK) (Cancer Research UK, 2012, Information Services Division, 2012). In 2009, more than 40,841 men were diagnosed with prostate cancer in the UK (Cancer Research UK, 2012), with 10,000 men dying from this disease. Prostate cancer for the most part is a disease of older men, and a diagnosis is less common for men below the age of 50 years (Burford et al., 2009).

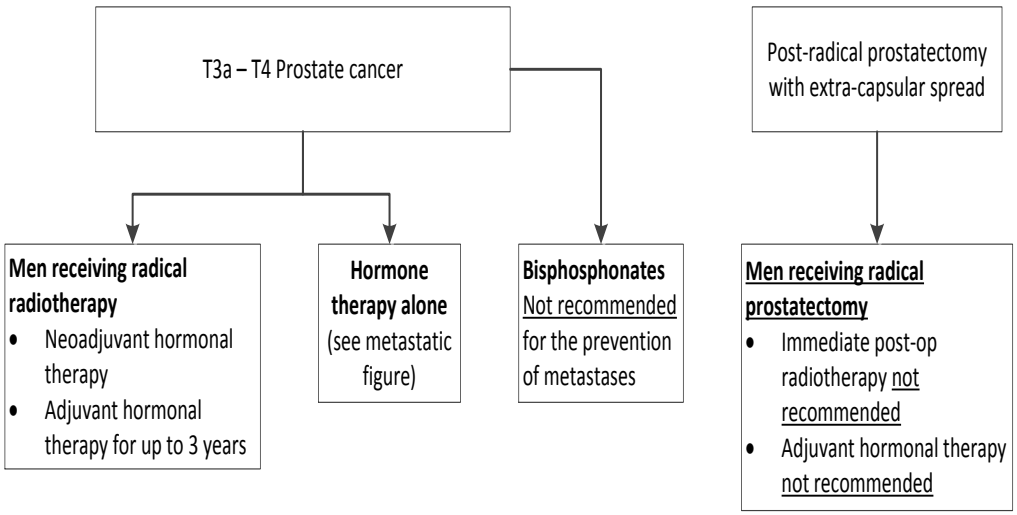
Four clinical procedures are commonly used to diagnose prostate cancer: digital rectal examination (DRE), the Prostate-Specific Antigen (PSA) blood test, trans-rectal ultrasound (TRUS) and needle biopsy (National Institute for Health and Clinical Excellence [NICE] 2008). There are three key prognostic factors relevant to prostate cancer: PSA, Gleason Score and Tumour-Nodes-Metastases (TNM) staging (NICE, 2008). PSA is a protein specifically produced by the prostate gland, and the PSA blood test results are usually reported as nanograms of PSA per millilitre (ng/mL) of blood. The Tumour-Nodes-Metastases (TNM) staging system is a way of recording how far the cancer has spread. The TNM staging system looks at the tumour (T), lymph nodes (N) and whether the cancer has metastasised (M) to other parts of the body. The Gleason system looks at the pattern of prostate cancer cells. There are five patterns which are graded from 1-5; a grade of 1 appears very similar to normal prostate tissue, whereas, a grade of 5 appears very different to normal tissue. The prostate biopsy samples are individually graded, and then, the two most commonly occurring patterns are added together to get a Gleason score of between 2-10. Low-grade cancers (a Gleason score of 6 or under) are usually slow-growing and less likely to spread. A Gleason score of 7 is a moderate grade and high-grade tumours (Gleason scores of 8-10) are likely to grow faster and more likely to metastasize. (NICE, 2008). The clinical presentation of these key prognostic factors informs the

treatment options available to men diagnosed with this disease (see table 1.1 and figures 1.1-1.2 for treatment overview), see NICE guidelines for in-depth clinical management.

Table 1.1 Treatment options available for localised prostate cancer

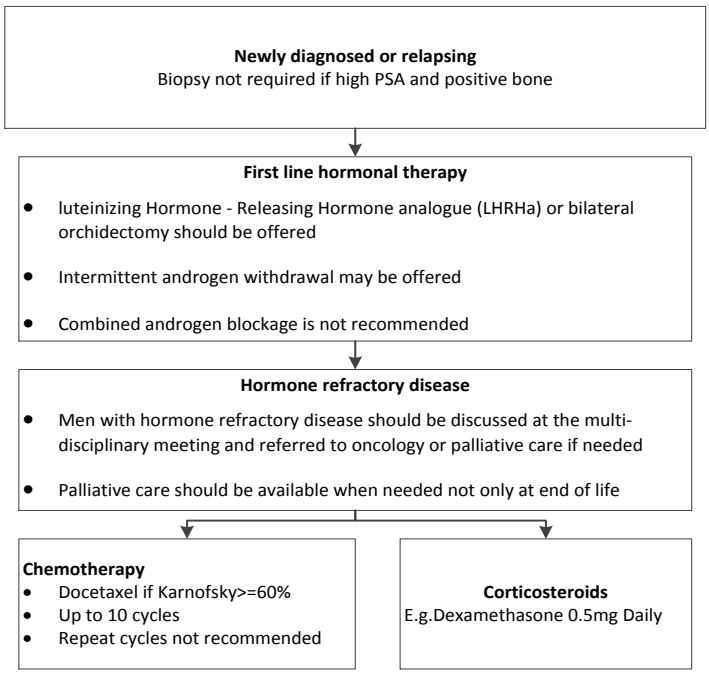
	Low-risk men (PSA ≤ 10ng/ml and Gleason score ≤ 6 and T1-2a	Intermediate risk men (PSA 10-20 ng/ml or Gleason score 7 or T2b-2c)	High-risk men (PSA ≥ 20ng/ml or Gleason score ≥ 8 to T3-T4)
Watchful waiting	◇	◇	◇
Active surveillance	✓	◇	X
Brachytherapy	◇	◇	X
Prostatectomy	◇	✓	✓
Radiotherapy	◇	✓	✓
Cryotherapy	X*	X*	X*
High-intensity focused ultrasound	X*	X*	X*

✓ Preferred treatment, ◇ Treatment Option, Not recommended, X*Not recommended other than in the context of clinical trials (NICE, 2008, p.34)



(NICE, 2008, p.34)

Figure 1.1 Treatment options available for locally advanced prostate cancer



(NICE, 2008, p.36)

Figure 1.2 Treatment options available for metastatic prostate cancer

There have been significant advancements in prostate cancer treatments that have reduced mortality rates (Gacci et al., 2009, Smith and Lindau, 2009, Jayadevappa et al., 2005). Now, not only is quantity of life important, but patients' quality of remaining life is crucial as men are living longer with this disease (Chen et al., 2009, Couper et al., 2009, Galbraith et al., 2008, Daubenmier et al., 2006, Dalkin et al., 2006, Brar et al., 2005, Feigenberg et al., 2005, Jayadevappa et al., 2005).

The disease and its treatments have the potential to cause substantial short- and long-term problems in this patient group (Maguire, 1989). The delicate nature of treatments mean that men with prostate cancer often face a host of difficulties which can negatively affect HRQoL (Eton and Lepore, 2002), including physical and psychological problems (Cockle-Hearne and Faithfull, 2010, Gerbershagen et al., 2008, Ene et al., 2006). Problems associated with prostate cancer treatments include: urinary (urgency, frequency, incontinence) (Zelefsky et al., 2008), bowel (rectal bleeding, urgency in defecation, diarrhoea, and faecal leakage) (Al-Abany et al., 2002) and sexual dysfunction (impotence, loss of libido) (Gomella, 2007). Other symptoms associated with therapies include: fatigue, weight gain, depression, osteopenia, anaemia, muscle atrophy, gynaecomastia, hot flushes and loss of

cognitive function (Cancer Research UK, 2011, Engstrom, 2008, Schneider et al., 2007, Engstrom, 2005). Due to increasing survival rates (Jemal et al., 2011, Burford et al., 2009) the number of men dealing with the aftermath consequences of prostate cancer are set to rise (Korfage et al., 2007). There is a growing concept of survivorship in people affected by cancer because many individuals will continue to live with long-term problems after treatment has finished. Macmillan Cancer Support define the concept of survivorship as,

"… someone who has completed initial cancer management and has no apparent evidence of active disease, or is living with progressive disease and may be receiving cancer treatment but is not in the terminal phase of illness (last six months of life), or has had cancer in the past".

(Davies and Batehup, 2010)

The Scottish Government (Department of Health Macmillan Cancer Support & NHS Improvement, 2010) acknowledges that further work is needed to fully understand the survivorship needs of individuals affected by cancer. This policy identifies that future work is needed to find ways of supporting and empowering patients, building confidence, and identifying sources of support which are needed to maintain the level of independence necessary for optimum quality of life. Prostate cancer and its treatments can have a profound negative effect on HRQoL. The identification of the predictor variables of HRQoL and how HRQoL changes over time is a helpful starting point to direct future research in this field for men living with and beyond prostate cancer.

Definitions of HRQoL

It is important to distinguish the different quality of life terms in the literature for the purpose of this thesis. Examples of HRQoL measures include: disease- or population-specific measures which are multi-domain and relevant to specific health problems such as cancer; the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate (van Andel et al., 2003); or generic measures which can be used across population types that are also multi-domain measures of broader health status, for example the Short Form-36 (Ware and Sherbourne, 1992).

Individualised measures of quality of life enable respondents to nominate and weigh important areas of their own life, for example, the Schedule for Evaluation of Individual Quality of Life (O'Boyle et al., 1993) or the Patient Generated Index (Ruta et al., 1994). The evaluation of quality of life is dynamic, multi-level and complex and clear use of quality of life terms are important to avoid confusion.

The World Health Organisation (1947) has defined health as not merely the absence of disease, but to also include complete physical function, social function, role function, mental health and general health perceptions. This early definition of health subsequently paved the way for HRQoL (O'Connor, 2004). An early definition of HRQoL has been defined as a multi-dimensional concept that encompasses the physical, emotional, and social components associated with an illness or treatment (Revicki, 1989). Elsewhere, HRQoL refers to the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatments (Cella and Nowinski, 2002). According to the World Health Organisation, HRQoL is a term used to describe psychological and social functioning as well as physical functioning and incorporates positive aspects of well-being as well as negative aspects of disease and infirmity (Sloan, 2002). To date, there is not a universally accepted definition of HRQoL (Bottomley, 2002, Bowling, 2001).

Yet, based on these definitions of HRQoL, it transpires that there is a consensus that HRQoL is a multi-dimensional construct that includes: physical, psychological and social aspects of patients' well-being. The Medical Research Council recommended that HRQoL assessments for patients with cancer should include the following: physical well-being (for example: symptoms, physical activity, self-care, toxicities' from treatments), psychological well-being (for example: emotional distress, depression, anxiety, mood) and social well-being (for example: effects on social activities, work, recreation, relationships with friends and family) (Maguire, 1989). In addition, researchers should implement a general HRQoL measure to evaluate the above multi-dimensional domains, supplemented with a disease-specific assessment.

The recommendations by the Medical Research Council to use multi-dimensional measures of HRQoL are supported in more recent literature (Bottomley, 2002) and

have been widely applied and reproduced in many prostate cancer studies (Roeloffzen et al., 2010, Namiki et al., 2009a, Smith et al., 2009, Zavala et al., 2009, White et al., 2008, Litwin et al., 2007a, Northouse et al., 2007a, Jayadevappa et al., 2007, Daubenmier et al., 2006, Brar et al., 2005). The rationale for assessing general multi-dimensional domains of HRQoL in addition to disease-specific domains of HRQoL is because HRQoL tends to differ according to the cancer stage and treatments (Kobuke et al., 2009, Cella and Nowinski, 2002). Incorporating measures in this way allows a sensitive and holistic evaluation of the problems associated with having prostate cancer, responsive to the stage of disease, and specific treatments (Bowling, 2001, Sommers and Ramsey, 1999, Hopkins, 1992). Finally, HRQoL instruments in prostate cancer should have demonstrated reliability and validity (Eton and Lepore, 2002, Sommers and Ramsey, 1999) (see table 1.2 for an overview of HRQoL instruments used in prostate cancer studies).

Table 1.2 Instruments Used to measure HRQoL in prostate cancer research

Instrument	Items	Cronbach's Alpha (range from low to high)	Mode of administration	Comments
Generic Measures of HRQoL				
Medical Outcomes Study 36-Item (Ware and Sherbourne, 1992) Used in: (White et al., 2008, Jayadevappa et al., 2006, Daubenmier et al., 2006, Ficarra et al., 2006)	36	low of 0.65 to high of 0.94	Self or interviewer	Eight scales measure physical, psychological and social functioning, including subjective mental health status and vitality, bodily pain and general health perceptions.
Nottingham Health Profile (NHP) *(Hunt and McEwan, 1980)* Used in: (Joly et al., 1998, Hunter et al., 1995)	38	low of 0.77 to high of 0 85	Self	Includes a number of subscales for energy, pain, emotional reactions, sleep, social isolation and mobility. The performance section includes occupation, home tasks, sex life, social life, hobbies, holidays and personal relationships.
<u>Cancer-specific measures of HRQoL</u>				
European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Cancer 30 (EORTC – C30) *(Aaronson et al., 1993)* Used in: (Galvao et al., 2010, Roeloffzen et al., 2010, Fransson, 2008, Buron et al., 2007, Choo et al., 2007, Van Gellekom et al., 2005, Fransson et al., 2001, Albertsen et al., 1997)	30	low of 0.70 to a high of 0.90	Self	Multiple domains are assessed, physical, role, emotional, cognitive and social functioning, individual symptoms (dyspnoea, insomnia, appetite loss, constipation, diarrhoea, nausea and vomiting, pain, fatigue). In addition financial difficulties related to cancer. A prostate cancer-specific

				supplement developed to address prostate specific problems.
Functional Living Index (FLIC) *(Schipper et al., 1984)* Used in: (Turner et al., 2001, Braslis et al., 1995, Lim et al., 1995, Cassileth et al., 1992)	22	low of 0.64 to high of 0.87	Self	Assess quality of life for patients undergoing their treatment. Assesses psychological, social and physical functioning.
Functional Assessment of Cancer Therapy – General (FACT-G) *(Cella et al., 1993)* Used in: (Ahles et al., 2004, Bradley et al., 2004, Knight et al., 2001, Tefilli et al., 1998, Esper et al., 1997, Shrader-Bogen et al., 1997)	28	low of 0.65 to high of 0.89	Self	Measures physical, social/family, emotional, functional well-being and the relationship with physician.
Rotterdam Symptom Checklist (RSCL) (de Haes et al., 1990) Used in: (Duncan et al., 2000)	27	low of 0.83 to high of 0.90	Self	Measuring psychological distress, activity level scale and overall evaluation of life for cancer patients.
Prostate Cancer-Specific Measures				
Functional Assessment of Cancer Therapy – Prostate (FACT-P) (Esper et al., 1997) Used in: (Fujimura et al., 2009, Arai et al., 2008, Joseph et al., 2008, Feigenberg et al., 2005)	47	Low of 0.65 to high of 0.69	Self	Measures sexual, bowel, bladder function and pain domains.
University of California at Los Angeles (UCLA) Prostate Cancer Index (Litwin et al., 1998a) Used in: (Namiki et al., 2009b, Namiki et al., 2008, Prezioso et al., 2007a, Yoshimura et al., 2007, Namiki et al., 2006a, Korfage et al., 2005, Kakehi et al., 2002)	20	Low of 0.65 to high of 0.93	Self	Measures sexual, urinary and bowel function and bother. It also assesses the overall satisfaction with the prostate cancer treatment.
Expanded Prostate Cancer Index (EPIC) (WEI et al., 2000) Used in: (Guedea et al., 2009, Sugimoto et al., 2009, Ash et al., 2007, Merrick et al., 2003)	32	Low of 0.74 to high of 0.94	Self	Measures sexual, urinary, and hormonal function and bother. It also measures satisfaction with treatment.
International Prostate Symptom Score (IPSS) (Barry et al., 1992) Used in: (Meyer et al., 2009, Ash et al., 2007, Feigenberg et al., 2005, Egawa et al., 2001, Lee et al., 2000)	7	Low of 0.86 to high of 0.92	Self	Designed for benign prostatic hyperplasia (BPH) assesses urinary symptoms only: frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying and urgency
European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Prostate (EORTC – PR25) (van Andel et al., 2008) Used in: (Berry et al., 2006, Geinitz et al., 2006, Vordermark et al., 2006)	25	Low of 0.70 To a high of 0.86	Self	Used in conjunction with the EORTC-C30, this measure assesses urinary, bowel, sexual symptoms and functioning, in addition to specific side-effects of prostate cancer treatment.

Cancer-specific HRQoL is an important research outcome in prostate cancer studies (Albaugh and Hacker, 2008, O'Connor, 2004, Adolfsson, 2003, Efficace et al., 2003,

Sloan and Varricchio, 2001, Bowling, 2001, Eton et al., 2001, Aaronson, 1988). Furthermore, cancer-specific HRQoL should be based on patients' own self-reports of their subjective experience of the multi-dimensional domains (O'Connor, 2004, Bowling, 2001, Bowling, 1991). Consequently, patients' thoughts, feelings, and ratings of their HRQoL cannot be assumed, and HRQoL should be rated from the patient's own self-reports (Litwin et al., 1998b, Lieberman et al., 1996, Sprangers and Aaronson, 1992, Jachuck, 1982).

In summary, the operational definition of HRQoL for this structured literature review is based on patients' *own self-reports* of the multi-dimensional domains of health, including *general* and *disease-specific* HRQoL, using standardised instruments.

1.3 Methodology

1.3.1 Aim

The overall aim of this review was to find out what predicts HRQoL for men affected by prostate cancer and how HRQoL changes over time.

Review questions

The review specifically was driven to answer the following questions:

1) What predicts HRQoL in men affected by prostate cancer?
2) How does HRQoL change over the prostate cancer journey?

1.3.2 Methods

A structured review of empirical evidence was conducted that aimed to include qualitative and quantitative research to generate a broad overview of existing knowledge in this area (Webb and Roe, 2007, Whittemore, 2005). This wide inclusion enabled a diverse range of methodologies to be included. Most traditional systematic review methodologies are limited to randomised control trials (RCT) and, therefore, would exclude prospective longitudinal evaluations of HRQoL for men affected by prostate cancer. While systematic reviews in their current format answer questions, for example which intervention works, it fails to adequately address some nursing questions related to caring or the impact of illness or treatment (McCourt, 2005, Thomas et al., 2004, Evans and Pearson, 2001, Dixon-Woods and Fitzpatrick, 2001, Black, 1996). A structured review was

chosen as an appropriate method that was well suited to address the research questions.

This review was based on guidance provided by the Centre for Reviews and Dissemination (2008) to ensure that the methods implemented were as rigorous and transparent as possible. The process for this review included nine steps:

1) Formulation of the research questions
2) Setting up the review team
3) Developing review protocol
4) Searching and identifying the research evidence
5) Rating the studies for inclusion based on inclusion/exclusion criteria
6) Data extraction using pro forma checklist
7) Quality assessment
8) Results synthesis
9) Dissemination

1.3.3 Literature review team

The review team consisted of members of the Ph.D. candidate's supervisory team. It is good practice to have a minimum of 2 reviewers involved to minimise bias and error during all stages of the review (The Cochrane Collaboration, 2009, Centre for Reviews and Dissemination, 2008, Bero et al., 1998). There were 3 reviewers working at all stages in this review.

1.3.4 Searching and identifying the research evidence

The search process began with searching the Database of Abstracts of Reviews of Effects (DARE) and the Cochrane Database of Systematic Reviews (CDSR). No previous work had addressed the specific aims and research questions for the current review and, therefore, undertaking the review was appropriate and necessary. The search strategy began with taking each research question and breaking it down into the key words as follows: prostate cancer, prostate carcinoma, health-related quality of life, quality of life, longitudinal, treatments, sexual function, well-being, depression, impotence, incontinence, bowel symptoms. The key words were mapped to each electronic database or by using the appropriate MeSH (medical subject heading) term. Truncation, wildcards and Boolean logic were used. Free searches using the key words were also undertaken to try and generate more hits.

Individual searches rather than combined database searches were undertaken because this ensured all relevant hits were identified. Citation searches and backward chain-linking were undertaken. The search strategy included searching a number of electronic databases (see table 1.3) and grey literature, such as: Google, unpublished theses, and finally, hand searching of relevant urological journals.

Table 1.3 Electronic databases searched

Applied Social Sciences Index and Abstracts (ASSIA)
British Nursing Index (BNI)
PsycInfo
Web of Science
Google Scholar
Cumulative Index to Nursing and Allied Health Literature (CINAHL)
MEDLINE
Scopus
EMBASE
Index to Theses
Database of Abstracts of Reviews of Effects (DARE)
Cochrane Database of Systematic Reviews (CDSR)

Guidance was provided on three occasions by a Medical Librarian (at the University of Dundee) to facilitate the search in accessing grey literature, because this is acknowledged as difficult for researchers to obtain (Webb and Roe, 2007).

1.3.5 Inclusion and exclusion of studies

Recent studies acknowledged that clinical practices and surgical techniques have changed significantly over the years, for example, introducing laparoscopic and robotic techniques and nerve-sparing surgery. Therefore, data presented in earlier papers will no longer be an accurate representation of patient reports in current healthcare due to out-dated clinical management (Osoba, 2011, Eton and Lepore, 2002, Litwin et al., 2001). As a result, only studies in the last 5 years would meet the inclusion criteria with the underpinning clinical rationale.

To promote an approach for synthesising the level of evidence presented in research studies, a grading hierarchy was used to assess the level of evidence presented. There are numerous grading hierarchy systems available that acknowledged experimental methods (RCTs) as the gold standard for evaluation. The Department of Health in the National Service Framework (2001) identified the “typologies of supporting evidence” which identify the levels of evidence by research design (see

table 1.4). This framework was used because it has been applied to both peer-reviewed and non-peer reviewed research (Anderson et al., 2004).

Table 1.4 Evidence categories used by the Department of Health in the National Service Framework

Typologies of supporting evidence
A1 Systematic reviews, which include at least one randomised control trial (RCT), e.g. systematic reviews from Cochrane. A2 Other systematic and high quality reviews. B1 Individual RCTs. B2 Individual non-randomized, experimental/interventional studies. B3 Individual well-designed non-experimental studies, controlling statistically if appropriate. Includes case control, longitudinal, cohort, matched pairs or cross-sectional random sample methodologies, and well-designed qualitative studies, well-designed analytical studies, including secondary analysis. C1 Descriptive and other research or evaluations not in B (e.g. convenience samples). C2 Case studies and examples of good practice. D Summary review articles and discussions of relevant literature and conference proceedings not otherwise classified.

Based on the typologies used within the Department of Health this review included research studies at the level of B3-A1 for inclusion in the current review. This review excluded studies at the level of evidence D-C1. See table 1.5 for a summary of inclusion criteria and rationales.

Table 1.5 Inclusion criteria

Criteria	***Rationale***
Levels of evidence B3-A1.	Allows for the inclusion of quantitative and qualitative methods, identifying the levels of evidence by study design.
Does this title/abstract identify predictor variables of HRQoL?	This is the 1st key focus of the review; to establish what the predictor variables are for HRQoL in men with prostate cancer.
Does this title/abstract indicate how HRQoL changes over time?	This is the 2nd key focus of the review; to establish how HRQoL changes over the prostate cancer patient journey. *The articles had to address, at minimum, one of the above questions to be considered for inclusion.*
Published between 2005- to current date.	Recent literature acknowledges that clinical practices have changed. Bias is possible when integrating patients' reports of HRQoL from some time back, as patients are no longer treated by those provisions. Thus, earlier HRQoL reports have the potential to be inaccurate in current healthcare.
English text only	Secondary to budget constraints due to translation costs.
Grey Literature	To try and minimise the risk of publication bias, and provide a detailed account of the HRQoL in prostate cancer.

Prostate cancer patients only	The papers would include studies that are focused on men with prostate cancer only; this is the primary context of the review and, as a result, other cancer sites would be excluded.
No limitation of the geographical country	To capture the broad range of HRQoL prostate cancer studies existing, worldwide.

The reviewers used a pro forma checklist to rate the titles and abstracts based on the inclusion criteria (see appendix 1.1 for pro forma checklist). The pro forma checklist was piloted among the review team. All of the references in the review were managed using the software package Endnote x4.

1.3.6 Quality assessment

The quality assessment of individual research studies is fundamental to a meaningful review (Verhagen et al., 2001, Harbour, 2001, Bero et al., 1998) and rating the levels of evidence alone is inadequate (Webb and Roe, 2007, Dixon-Woods et al., 2005). However, there is little agreement on how to quality assess studies with diverse methodologies (Dixon-Woods et al., 2005). A recent review funded by the Health Technology Assessment (Shaw et al., 2009) developed two quality assessment tools for diverse methodologies, one quality assessment tool for qualitative methods, and one quality assessment tool for quantitative methods. Shaw's quality assessment tools were applied to this review (see appendix 1.2).

The quality assessment provided a relative quality rating, rather than an absolute quality rating (Verhagen et al., 2001). To minimise the potential for bias, the quality assessment tools were piloted on full-text research studies to establish agreement among the reviewers on the application of the quality assessment tools.

1.3.7 Data extraction

Key information from the studies was extracted using narrative data extraction sheets. The key information extracted is identified in table 1.6. The data extraction sheets provided consistency in the data extracted from studies and was designed based on recommendations from Cochrane guidelines and the Centre for Reviews and Dissemination (The Cochrane Collaboration, 2009, Centre for Reviews and Dissemination, 2008).

Table 1.6 Data extraction

Unique reference number (for reviewers' reference)
Authors (s)
Year of publication
Country
Overall aim of the study
Participants characteristics (age, race, education, social class, cancer stage, cancer treatments)
Number of patients approached, and the number of patients consented (identify the possibility of selection bias)
Methods – study design, time points for data collection, measures (variables in the study), intervention details, method of randomisation, and participants' attrition rates.
Overall findings and conclusions
Limitations

1.3.8 Evidence synthesis

A narrative synthesis and tabulation of primary research studies was used to generate broad findings and conclusions (Webb and Roe, 2007). More specifically, the review undertook the steps (see table 1.7) to provide a thorough interpretation of primary sources, as suggested by Whittemore (2005). The recommendations of Whittemore have been applied to several reviews (Flinkman et al., 2010, Da Silva et al., 2010, Walsh et al., 2009, Kennedy et al., 2008), and provide a basis to promote rigour in combining diverse evidence sources.

Table 1.7 Key steps in the analysis

Elements	Description
Data reduction	*This phase involved managing the data from the primary sources. The review used a sub-group classification, initially separating the qualitative and quantitative evidence, and then grouping the levels of evidence (for example; all observational studies, and all of the intervention RCTs). These groups were then sub-grouped, into studies that identified predictors and change of HRQoL over time. This phase enabled analysis by topic and research question.*
Data comparison	*This stage was an iterative process of examining the tabulated data in order to identify patterns, themes or relationships. This required a number of strategies, such as counting, making comparisons, and establishing common and unusual findings from primary sources.*
Conclusion drawing and verification	*This is the final stage in the analysis. Once patterns and relationships have been established, this stage required confirmation from the primary data sources for accuracy and confirmability.*

1.4 Findings

Based on recommendations for the Preferred Reporting of Items for Systematic Reviews and Meta-analyses (PRISMA statement), the flowchart below (see figure 1.3) illustrates the data identification and data synthesis for this review (Moher, 2009).

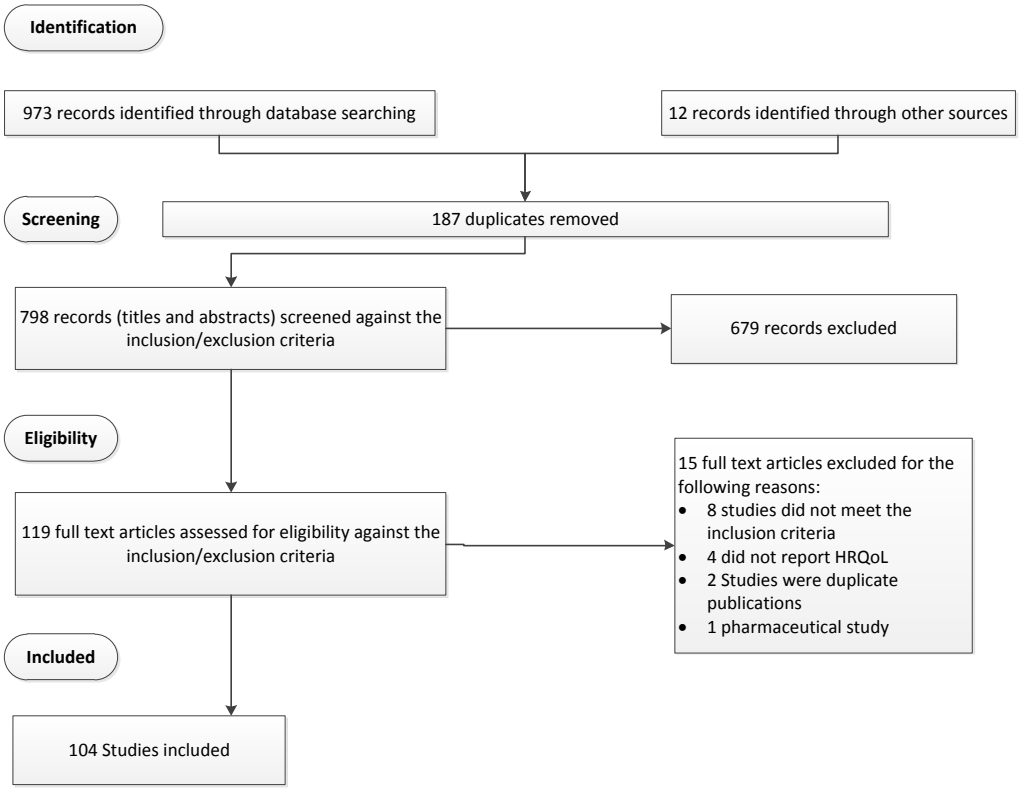


Figure 1.3 PRISMA: Flow of information through the different phases of the HRQoL review (Moher, 2009)

Inter-rater reliability analysis was established using the Kappa statistic in two steps. The ratings of the initial application of the inclusion/exclusion pro forma checklist was found to be Kappa = 0.64 ($p < .0.001$). Discussions then took place to review areas of disagreement on the application of the pro forma checklist on the publications. The Kappa statistic was then reapplied and was Kappa = 0.94 ($p < .0.001$) which demonstrates an almost perfect level of agreement (< 0 less than chance of agreement, 0.01-0.20 slight agreement, 0.21-0.40 fair agreement, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, 0.81-0.99 almost perfect agreement (Viera and Garrette, 2005). Disagreement was generally a result of slightly different interpretations of the title/abstracts of the reviewed publications. A consensus was reached by discussion in all cases.

The kappa statistic was unsuccessful in determining the reviewer consistency of the application of the quality assessment checklists. This was because the reviewer data in SPSS was asymmetrical in the Chi-squared tables. This issue has been reported elsewhere (Pikora et al., 2002). The level of agreement was calculated by hand using the formula, *agreements/ (agreements + disagreements) x 100 (Araujo, 1985).* The percentage of agreement in the quality assessment of research studies was 83.3% agreement. Disagreement was generally a result of slightly different interpretations. A consensus was reached by discussion in all cases.

Altogether, 104 papers were included in the review (see appendix 1.3 for data extracted). One-hundred-and-four papers are a large number and this reflects the growth in worldwide research in this area, and reinforces the pressing need to take account of the evidence. The findings will address the following research questions:

1) What predicts HRQoL in men affected by prostate cancer?
2) How does HRQoL change over the prostate cancer journey?

1.4.1 Predictors of HRQoL

There were a range of methodologies (see table 1.8) all using quantitative methods which identified predictors of HRQoL. The 53 studies were conducted in America (39), Canada (2), Italy (2), Netherlands (1), Germany (1), Australia (2), Japan (4), UK (1) and Sweden (1). Sample sizes ranged from N=30 to N=1642 with a total sample size of N=16,689 in the 53 review papers.

Table 1.8 Methodologies of studies identifying predictors of HRQoL

Type of study	*Number*
Prospective longitudinal	39
Intervention/RCT	10
Prospective longitudinal with match controls	3
Cross-sectional random samples	1

Studies have identified predictor variables for HRQoL across all stages of prostate cancer - localised, locally advanced and metastatic. There are very few studies that have identified predictors of HRQoL in relation to specific treatment modality. Consequently, it was not possible to identify the predictors of HRQoL for each treatment modality and therefore, the findings will be presented based on cancer stage.

Predictors of general HRQoL

The predictors of general HRQoL for men with localised prostate cancer can be classified into three groups of variables: demographic, clinical and psycho-social variables. These are summarised in table 1.9.

Table 1.9 Localised prostate cancer predictors of general HRQoL

Demographic variables predictive of higher HRQoL: Employed: (Diefenbach et al., 2008‡) Married: (Diefenbach et al., 2008‡) Younger men: (Lev et al., 2009‡, Diefenbach et al., 2008‡, Eller et al., 2006‡) White ethnic origin: (Lev et al., 2009‡, Diefenbach et al., 2008‡, Eller et al., 2006‡) **Demographic variables predictive of lower HRQoL:** Lower education level was associated with a lower HRQoL: (Ficarra et al., 2006§)
Clinical variables predictive of a lower HRQoL: Higher Gleason score: (Diefenbach et al., 2008‡) Co-morbidities: (Sanda et al., 2008‡, Gacci et al., 2008‡) Larger prostate gland: (Gacci et al., 2008‡) Disease-specific domains: urine, bowel and sexual function (Queenan et al., 2010§, Eller et al., 2006‡, Lev et al., 2004§) **Individual treatments predictive of a lower HRQoL:** Hormone therapy: (Sanda et al., 2008‡, Prezioso et al., 2007b§) Radical prostatectomy is more likely to reduce HRQoL compared to laparoscopic radical prostatectomy: (Miller et al., 2007‡) Radical prostatectomy is more likely to reduce HRQoL compared to Brachytherapy: (Kobuke et al., 2009§) Other studies report not finding any relationship between the clinical variables: PSA, Gleason score, pathological stage, (Kobuke et al., 2009§) and treatment (Litwin et al., 2007§) with HRQoL.
Psycho-social variables predictive of lower HRQoL: Depression: (Lev et al., 2009‡, Eller et al., 2006‡) Perceived stress: (Eller et al., 2006‡) **Psycho-social variables predictive of higher HRQoL:** Coping styles (positive attitude): (Eller et al., 2006‡) Self-efficacy: (Roberts et al., 2006‡) Social support:(Roberts et al., 2006‡)

Key: ‡ multivariate analysis used, § correlational analysis used

Only two studies in this review assessed predictors of locally advanced cancer. The remaining studies included mixed populations of men with localised and locally advanced prostate cancer participants. The predictors of general HRQoL for localised/locally advanced prostate cancer are summarised together in table 1.10.

Table 1.10 Localised/locally advanced prostate cancer predictors of general HRQoL

Demographic variables predictive of lower HRQoL
Increasing age: (White et al., 2008‡, Krupski et al., 2005a‡, Miller et al., 2005‡)
Hispanic/African American ethnic origin: (Jayadevappa et al., 2007‡, Krupski et al., 2005b‡)
Demographic variables predictive of higher HRQoL:
White ethnic origin: (Jayadevappa et al., 2006‡)
Higher education: (Jayadevappa et al., 2006‡)
Married: (Jayadevappa et al., 2006‡)
Clinical variables predictive of a lower HRQoL:
Co-morbidity: (Poll-Franse, 2008§, Krupski et al., 2005a‡)
Higher Gleason score: (Jayadevappa et al., 2006‡, Brar et al., 2005‡)
Higher Tumour Node Metastases (TNM) classification: (Jayadevappa et al., 2006‡)
Individual treatments predictive of a lower HRQoL:
Hormone therapy: (Lips et al., 2007‡)
Radical prostatectomy: (Krupski et al., 2005a‡)
Conformal radiotherapy had lower HRQoL compared to intensity modulated radiotherapy: (Lips et al., 2007‡)
Laparoscopic radical prostatectomy: (Miller et al., 2007‡)
Psycho-social variables predictive of lower HRQoL:
Depression: (Monahan et al., 2007‡)
Predictors for higher HRQoL:
Social support: (Queenan et al., 2010 §)

Key: ‡ multivariate analysis used, § correlational analysis used

Seven studies identified predictors of general HRQoL for men with metastatic prostate cancer. Three studies included samples with all stages of disease (localised, locally advanced and metastatic disease). For the summary of the predictor variables see table 1.11 for summary.

Table 1.11 Metastatic prostate cancer predictors of general HRQoL

Demographic variables predictive of lower HRQoL:
Increasing age: (Spry et al., 2006)
Clinical variables predictive of a lower HRQoL:
Higher TNM classification: (Berglund et al., 2007§)*
Metastatic disease: (Berglund et al., 2007§)*
Skeletal morbidity: (DePuy et al., 2007‡)
Hormone therapy: (Spry et al., 2006§)
Patients with metastatic cancer who had better HRQoL scores predicted better survival: (Sullivan et al., 2006‡)
Psycho-social variables predictive of higher HRQoL:
Spirituality: (Zavala et al., 2009‡)
Positive coping (active coping): (Kershaw et al., 2008‡)*

*Studies that included all stages of disease.

Key: ‡ multivariate analysis used, § correlational analysis used

Predictors of prostate cancer-specific HRQoL

The findings for predictor variables of prostate cancer-specific HRQoL (urinary, bowel and sexual dysfunction) for men with localised disease are summarised in table 1.12.

Table 1.12 Localised prostate cancer predictors of prostate cancer-specific HRQoL

Predictor variables for worse urinary function*:*
Demographic:
African American ethnic origin: (Sanda et al., 2008‡)
Increasing age: (Namiki et al., 2009c‡, Sanda et al., 2008‡)
Clinical:
Hormone therapy: (Roeloffzen et al., 2010‡)
Initial prostate specific antigen (PSA) level: (Roeloffzen et al., 2010‡, Sanda et al., 2008‡)
Co-morbidity: (Namiki et al., 2009d‡)
Brachytherapy patients are more likely to experience urinary irritation and obstruction than men treated with radiotherapy: (Pinkawa et al., 2009a‡)
Nerve-sparing surgical techniques were not predictive of an improved urinary function: (Rogers et al., 2006‡, Dalkin et al., 2006‡)
Predictor variables for worse bowel function:
Demographic:
Increasing age: (Sanda et al., 2008‡)
Clinical:
Larger prostate size: (Roeloffzen et al., 2010‡, Sanda et al., 2008‡)
Neoadjuvant hormone therapy: (Sanda et al., 2008‡)
Co-morbidity: (Sanda et al., 2008‡)
Radiotherapy patients are more likely to experience proctitis than brachytherapy patients: (Pinkawa et al., 2009a‡)
Predictor variables for worse sexual function:
Demographic:
Increasing age: (Roeloffzen et al., 2010‡, Sanda et al., 2008‡)
Clinical:
Initial PSA level: (Roeloffzen et al., 2010‡, Sanda et al., 2008‡)
Hormone therapy: (Roeloffzen et al., 2010‡, Smith et al., 2009‡)
Radical prostatectomy: (Sanda et al., 2008‡)
Better sexual functioning:
Nerve-sparing techniques: (Sanda et al., 2008‡, Rogers et al., 2006‡)

Key: ‡ multivariate analysis used, § correlational analysis used

The findings for predictor variables of prostate cancer-specific HRQoL (urinary, bowel and sexual dysfunction) for men with localised/locally advanced disease are summarised in table 1.13.

Table 1.13 Localised/locally advanced prostate cancer predictors of prostate cancer-specific HRQoL

Predictor variables for worse urinary function: **Demographics** Older age: (Miller et al., 2005‡) Lower education level: (Jayadevappa et al., 2005‡) African/American ethnic origin: (Jayadevappa et al., 2007‡) Country of residence: (Namiki et al., 2009a‡) **Predictor variables for better urinary function:** Married was predictive of better urinary function: (Jayadevappa et al., 2005‡) **Clinical** Radical prostatectomy: (Namiki et al., 2009d‡, Jayadevappa et al., 2007‡, Monahan et al., 2007‡, Krupski et al., 2005a‡) Smaller prostate size: (Pinkawa et al., 2009b‡) Hormone therapy: (Pinkawa et al., 2009c‡, Wu et al., 2008‡) Radiotherapy: (Jayadevappa et al., 2007‡) **Psycho-social:** Depression: (Monahan et al., 2007‡)
Predictor variables of worse bowel function: **Demographics** Hispanic ethnic origin: (Krupski et al., 2005b‡) **Clinical** Radiotherapy: (Jayadevappa et al., 2007‡) Co-morbidity: (Jayadevappa et al., 2005‡) Treatment: (Wu et al., 2008‡, Jayadevappa et al., 2005‡) **Psycho-social:** Depression: (Monahan et al., 2007‡)
Predictor variables of worse sexual function: **Demographics** Age: (Krupski et al., 2005a‡) Married: (Jayadevappa et al., 2005‡) **Clinical** RP: (Namiki et al., 2009c‡, Jayadevappa et al., 2007‡, Krupski et al., 2005a‡) Co-morbidities: (van de Poll-Franse et al., 2008a‡, Jayadevappa et al., 2006‡) Baseline sexual function: (Jayadevappa et al., 2005‡) Transforming Growth Factor beta1/physiology (TGFBI) genotypes: (Peters et al., 2008‡) Hormone therapy: (Stephens et al., 2007‡, Wu et al., 2007‡) Nerve-sparing surgical techniques improves sexual function: (Namiki et al., 2009c‡, Inoue et al., 2009‡) **Psycho-social:** Depression: (Monahan et al., 2007‡)

Key: ‡ multivariate analysis used, § correlational analysis used

The findings for predictor variables of disease-specific HRQoL (urinary, bowel and sexual dysfunction) for men with metastatic cancer are summarised in table 1.14.

Table 1.14 Metastatic prostate cancer predictors of prostate cancer-specific HRQoL

Predictor variables for worse urinary function: **Demographics** Increasing age: (Gacci et al., 2009 ‡) **Clinical** Higher PSA level : (Gacci et al., 2009 ‡) TNM classification: (Gacci et al., 2009 ‡) Hormone therapy: (Gacci et al., 2009 ‡)
Predictor variables of bowel function: There were no predictor variables identified from primary research studies.
Predictor variables for worse sexual function: **Demographics** Increasing age: (Gacci et al., 2009 ‡) **Clinical** PSA: (Gacci et al., 2009 ‡) TNM classification: (Gacci et al., 2009 ‡) Gleason Score: (Gacci et al., 2009 ‡) Hormone therapy: (Gacci et al., 2009 ‡) Nerve-sparing surgical techniques predictive of better sexual function: (Gacci et al., 2009 ‡)

Key: ‡ multivariate analysis used, $ correlational analysis used

Interventions aimed at improving HRQoL

In total there were 10 intervention studies (Galvao et al., 2010, Parker et al., 2009, Berglund et al., 2007, Northouse et al., 2007b, Monga et al., 2007, Culos-Reed et al., 2007, Daubenmier et al., 2006, Zhang et al., 2006, Carmack Taylor et al., 2006, Penedo et al., 2006) that aimed to improve HRQoL. These papers had a limited scope in the geographical areas that they were conducted in ranging from: seven in America, one in Australia, one in Sweden, and one in Canada. None of the reviewed studies were conducted in the UK. The intervention studies aimed to improve HRQoL were grouped together according to the type of intervention, namely: 1) physical activity, 2) stress management and 3) lifestyle and supportive interventions.

Studies that delivered *physical activity*, *strength training and aerobic exercise* (Galvao et al., 2010, Berglund et al., 2007, Monga et al., 2007, Culos-Reed et al., 2007) reported different intervention effects on HRQoL (see appendix 1.3 for full intervention details). Galvao's intervention consisted of progressive resistance and aerobic training delivered twice a week by exercise physiologist (Galvao et al., 2010). The study sample (N=57) was heterogeneous in clinical characteristics and the time since diagnosis was not reported. The control group was standard care but there was no description of what standard care was. A significant intervention effect was found

for a HRQoL for general health, vitality, physical health (as measured by SF-36), and physical role and cognitive function (as measured by the EORTC-C30). There are a number of limitations to this study that are worthy of acknowledgment. Prostate cancer-specific symptoms were not assessed in this study and therefore, changes in urinary, bowel and sexual dysfunction remain unknown. The follow-up was limited to 12 weeks after the intervention and, therefore, it is unclear whether or not the intervention effect would be sustained in the longer term, such as one year and beyond. Lastly, as part of the inclusion criteria, the study participants had to be able to walk 300m and this limits the generalisabilty of the findings to less physically able men.

A further intervention delivered an exercise programme 3 times per week for a total of two months (Monga et al., 2007). The participants (n=11) exercised in the morning before their radiotherapy by performing a 10-minute warm-up, 30 minutes of aerobic exercise and 10 minutes of cool-down. A significant intervention effect was found on improved HRQoL (as measured by the FACT-G) for physical function, physical well-being and social well-being compared to the control group (n=10). The control group was blinded to the intervention arm and received standard care. There was no description of what standard care was. The study sample was very small and limits the generalisabilty of the findings. Furthermore, the follow-up was limited to completion of radiotherapy treatment, consequently the long-term changes in HRQoL are not known.

The third reviewed exercise intervention study (Culos-Reed et al., 2007) provided a 12-week individualised fitness programme (n=31) delivered by a certified fitness professional. In addition, group-based exercise classes were conducted every two weeks over the 12-week intervention. The study sample had heterogeneous clinical characteristics and the mean time since diagnosis was 33.9 months (SD 42.1). HRQoL (as measured by EORTC C30) improved for physical function, social function and fatigue from before the intervention to after the intervention (12 weeks). At four months post-intervention, global HRQoL was significantly worse than pre-intervention scores. The findings suggest that long-term benefits of exercise interventions are not maintained. There are a number of important methodological limitations to this study that are worthy of discussion. This study did not have a

control group and, therefore, the findings are treated with caution because in the absence of a comparison group it is impossible to know how HRQoL would have been affected without the intervention. Prostate cancer-specific HRQoL was not assessed in Culos-Reed's study and it is possible that urinary, bowel or sexual dysfunction may have predicted worsening global HRQoL (Culos-Reed et al., 2007). Lastly, physical activity was assessed using a self-report questionnaire and the bias of this approach could have been minimised by using a pedometer as an objective assessment of physical activity.

The last reviewed exercise intervention study (Berglund et al., 2007) had 4 study groups: 1) physical exercise delivered by a physiotherapist, 2) information provision delivered by a specialist nurse, 3) combined physical exercise and information provision and 4) control group which was standard care. The study sample (N=211) had different clinical characteristics and were all recruited within 6 months of their prostate cancer diagnosis. No intervention effect was identified for the 3 study conditions on improved HRQoL as measured by the EORTC C30. The randomisation procedure was not described and, therefore, bias is possible in the allocation of participants to the study conditions. Selection and attrition biases are possible and limit the generalisabilty of the study findings. Lastly, prostate cancer-specific HRQoL was not measured and the intervention effect on urinary, bowel and sexual dysfunction are unclear and will remain unknown.

Stress-management interventions (Parker et al., 2009, Daubenmier et al., 2006, Penedo et al., 2006) reported different intervention effects on HRQoL. Daubenmier's study intervention aimed to educated men on stress management skills and healthy lifestyle changes through diet and exercise. The study sample (N=93) were men with localised prostate cancer on the active surveillance programme. Daubenmier used a minimisation approach to randomisation for the intervention arm (n=44) and to the control group (n=49) and, therefore, lacks proper randomisation and may have introduced bias in the results. No intervention effect was found for improved HRQoL as measured by SF-36 and the UCLA-PCI. The study sample was biased in favour of white educated men and limits the generalisabilty of the findings to other minority groups. Selection and attrition bias are likely in this study and the study sample was not representative of the wider population.

Parker's intervention study (Parker et al., 2009) had three study groups: 1) stress management delivered by a clinical psychologist, 2) supportive attention for psycho-social and medical history delivered by a clinical psychologist, and 3) standard care (see appendix 1.3 for further intervention detail). The study sample (N=164) were men undergoing radical prostatectomy for localised/locally advanced prostate cancer. HRQoL was assessed using SF-36 and UCLA-PCI at one month before surgery, one and six weeks after surgery, and six and twelve months after surgery. The participants in the stress management arm had higher physical function (SF-36) at twelve months compared to the two other study conditions (supportive attention and standard care). No additional significant differences were identified between the study condition for HRQoL scores (general and prostate cancer-specific).

The last stress management intervention study (Penedo et al., 2006) delivered a ten-week cognitive-behavioural stress management programme that included the following: coping strategies, assertiveness skills, relaxation skills and breathing exercises. A clinical psychologist delivered the intervention to men (mean time since diagnosis 16 months, SD 4.9) diagnosed with localised prostate cancer treated by either radical prostatectomy or radiotherapy. A significant intervention effect was found for improved HRQoL (as measured by FACT-G) for physical well-being, emotional well-being, global well-being and sexual function (as measured by the EPIC). Penedo's study follow-up was restricted to after the intervention and, therefore, the longer-term influence of the intervention on HRQoL is unknown. Penedos' study screened for major cognitive impairment, and used this as an exclusion criterion. This exclusion limits the generalisabilty of the findings to more psychologically compromised individuals. This is a limitation, and the results may not reflect the ageing population of men with prostate cancer with its likelihood of co-morbidity.

Lifestyle/educational and *supportive* intervention studies (Zhang et al., 2007, Northouse et al., 2007b, Carmack Taylor et al., 2006) did not report any improvements in HRQoL. Zhang's intervention (Zhang et al., 2007) had two study conditions: 1) a social support group which lasted for 1-2 hours facilitated by a clinical psychologist and 2) biofeedback sessions to teach pelvic floor exercises by a physiotherapist. No intervention effect was found on HRQoL as measured by SF-36,

or for improved urinary incontinence as measured by a visual analogue scale. This study did not have a control group and therefore, the findings are treated with caution because in the absence of a comparison group it is impossible to know how HRQoL would have been affected without the intervention. Prostate cancer-specific HRQoL was not assessed using a validated instrument and caution is taken in the interpretation of the results. A final limitation to this study was that the study was underpowered (N=29) and biased in favour of white educated men and thus limits the generalisabilty of their findings.

The third supportive intervention study (Northouse et al., 2007b) had two study conditions: 1) supportive/educational intervention, and 2) a control group which was standard care. The intervention included the following: coping skills, optimistic attitude, uncertainty reduction and symptoms management delivered by a specialist nurse. No intervention effect was found for improved HRQoL as measures by the FACT-G and FACT-P. There are a few limitations to this study. All of the study participants (N=263) were married and, therefore, the results are not generalisable to single men. Importantly, the randomisation procedure was not described in sufficient detail; consequently bias is possible in the allocation of study participants to the study arms. As a result, caution is taken in the interpretation of these findings.

The final intervention study reviewed (Carmack Taylor et al., 2006) had three study conditions: 1) lifestyle programme which educated men about regular exercise, healthy diet through goal setting and coping skills, 2) the educational social support group discussed the side effects of treatment and prostate cancer, and 3) control group was standard care. The study sample (N=134) consisted of men treated by hormone therapy for a mean time of 32.7 months and the time since diagnosis was not reported. Overall, no significant difference was found between the three study conditions at 6 and 12 months for HRQoL as measures by the SF-36. This study did not measure prostate cancer-specific HRQoL and, consequently, the intervention effect on urinary, bowel and sexual dysfunction was not assessed. Selection bias was also possible for this study and limits the generalisabilty of the findings.

It is unclear why the three intervention studies (Carmack-Taylor, Northouse, and Zhang) did not find any improvements for HRQoL. One possible explanation to

account for these findings is due to the homogeneous nature of marital and educational demographics across the three studies. Approximately 80-100% of the participants across the three studies were married, and over 76% had completed college degrees. As a result, it is possible that participants had high perceived social support due to being married, and, as a result, the supportive intervention had little impact. Furthermore, due to their being educated, it is possible individuals were self-sufficiently proactive in lifestyle modifications and sourcing educational materials, and further information/education had little impact.

1.4.2 HRQoL change over time

All of the studies that reported changes in HRQoL over time had a prospective longitudinal design (see table 1.14 for quantitative methods). In total, 77 studies assessed change over time and were conducted in America (42), Japan (13), Netherlands (6), UK (3), Canada (3), Sweden (2), Italy (2), Germany (2), Australia (2), Spain (1), and France (1). Sample sizes ranged from N=46 to N=2204 with a total sample size of N=23,381 across all of the studies.

Table 1.15 Methodologies of studies identifying change overtime for HRQoL

Type of study	*Number*
Prospective longitudinal	70
Prospective longitudinal with match controls	7

The studies that report changes over time have been grouped together by specific treatment modality. This grouping allowed a systematic and thorough understanding of the changes in general and prostate cancer-specific HRQoL based on individual treatments.

Radical prostatectomy

Measures used to assess general HRQoL for men treated by radical surgery included the SF-36, FACT-G and the EORTC C30. Overall, general domains of HRQoL are affected in the short-term, but recovery is reported during three and six months post-surgery. The physical component (as measured by the SF-36) significantly ($P<0.001$) worsened at six weeks (Kouba et al., 2007) and at three months post-surgery (Namiki et al., 2005a). Role-physical functioning and vitality (as measured by the SF-36) significantly worsened from before treatment to assessment at three months (Inoue et al., 2009, Jayadevappa et al., 2006, Namiki et al., 2005a). Social

well-being (as measured by FACT-G) also significantly worsens at three months post-surgery (Ward-Smith and Mehl, 2007). However, a rapid recovery is identified at three months after surgery for most general domains of HRQoL (Hashine et al., 2008, Namiki et al., 2008, Miller et al., 2007, Ene et al., 2006). Other researchers identify recovery of HRQoL at six months post-surgery (Kobuke et al., 2009, Inoue et al., 2009, Buron et al., 2007, Namiki et al., 2006a, Jayadevappa et al., 2006, Namiki et al., 2005a). Not all of the reviewed studies assessed HRQoL at both three and six months. Therefore, it is only possible to say that general domains of HRQoL for men treated by surgical techniques are likely to recover sometime between three and six months post-surgery.

Financial difficulties, pain levels, physical functioning and social functioning (as measured by EORTC C30) (Davison et al., 2007) were significantly worse at twelve months post-surgery than before treatment. Other longitudinal studies have demonstrated recovery of HRQoL to pre-treatment score (all multidimensional domains) at twelve months post-surgery (Guedea et al., 2009, Ficarra et al., 2006, Dalkin et al., 2006, Soderdahl et al., 2005) that is maintained through to twenty-four months (Guedea et al., 2009, Dalkin et al., 2006). One explanation that may explain the different results in Davison's study was that 30% of study participants received adjuvant hormone therapy. Due to the effects of adjuvant hormone therapy, men may have reported worse HRQoL compared to men who had surgery alone. Therefore, this bias may have influenced Davison's findings. In summary, there is a trend of recovery of general HRQoL that occurs somewhere between 3-6 months, that is maintained at longer term follow-up, but most domains of HRQoL have recovered to pre-treatment levels at twelve months post-surgery, with the one exception being for men on adjuvant hormone therapy.

Prostate cancer-specific HRQoL was measured using the EPIC, UCLA-PCI and EORTC-PR25 for men treated by radical surgery. Obstructive and irritative urinary symptoms are experienced at one month post-surgery, with recovery of symptoms at three months (Guedea et al., 2009). Men treated by surgical techniques often experience urinary incontinence, that is to say, at one month (Guedea et al., 2009), three months (Inoue et al., 2009), six months (Ball et al., 2006), twelve months (Namiki et al., 2006a, Latini et al., 2006), twenty-four months (Guedea et al., 2009, Buron et al.,

2007), thirty-six months (Chen et al., 2009), forty-eight months and sixty months (Namiki et al., 2006b) after surgery. The prevalence of urinary incontinence has been reported to be 20% of patients at three months, 12% at six months, and 8% at twelve months (Ficarra et al., 2006), with longer follow-up data identifying 8% of men are still incontinent at five years (Inoue et al., 2009). Patients treated by surgical techniques experience significantly worse urinary incontinence compared to brachytherapy (Guedea et al., 2009, Buron et al., 2007, Soderdahl et al., 2005) and radiotherapy (Guedea et al., 2009).

To clarify, the magnitude of urinary incontinence in the longer term, studies have measured incontinence pad usage. Most men (88%) reported that they did not use incontinence pads at twelve months post-surgery, with little change at twenty-four months (89%) (Dalkin et al., 2006, Rogers et al., 2006). Men who do wear pads at twelve months often do not truly need them for incontinence, but often use them as a safety liner (Dalkin et al., 2006). Consequently, assessment of urinary incontinence by counting pad usage is problematic and may not accurately detail the frequency of incontinence.

Sexual dysfunction is the other major problem for men treated with surgery. Studies have identified an increase in sexual problems at three months (Kouba et al., 2007, Namiki et al., 2005b), six months (Buron et al., 2007, Diefenbach and Mohamed, 2007, Kouba et al., 2007, Namiki et al., 2005a), twelve months (Kobuke et al., 2009, Diefenbach and Mohamed, 2007, Dalkin et al., 2006, Latini et al., 2006, Soderdahl et al., 2005, Namiki et al., 2005b), twenty-four months (Namiki et al., 2009c, Dalkin et al., 2006), thirty-six months, forty-eight months, and sixty months, (Namiki et al., 2009c) compared to pre-surgery patient reports. There is some evidence to suggest that nerve-sparing surgical techniques may improve penile rehabilitation for some men. One study identified that 60.5% of men treated by nerve-sparing LRP were engaging in intercourse at twelve months (Rogers et al., 2006). However, sexual dysfunction is prevalent over time despite the surgical approach used (open RP, LRP and Da Vinci Robotic prostatectomy) (Ball et al., 2006). Furthermore, sexual dysfunction is common in men before surgery (Guedea et al., 2009, Davison et al., 2007, Buron et al., 2007). Comparison studies have shown that men treated by

surgery report the worse sexual function at twelve months compared to brachytherapy (Namiki et al., 2006b, Soderdahl et al., 2005).

Men with locally advanced disease treated with RP and adjuvant hormone therapy report more severe bowel, urinary and sexual dysfunction at 6 weeks, twelve months, twenty-four months, thirty-six months, forty-eight months and sixty months, compared to surgery alone (Moinpour et al., 2008).

Brachytherapy (BT)

Measures used to assess general HRQoL for men treated by BT included the SF-36, FACT-G and the EORTC C30. Short-term declines in general HRQoL domains are experienced at two months after BT with recovery in HRQoL at six months, that is maintained through to twelve months (Vordermark et al., 2009, Soderdahl et al., 2005), eighteen months, and twenty-four months (Buron et al., 2007). Role functioning and pain has been reported to gradually worsen over time in this patient group, at both, six and twelve months after treatment (Van Gellekom et al., 2005). Improvements in emotional functioning have been reported at the following trajectories: one, six, twelve and twenty four-months with patient scores exceeding pre-treatment scores at twenty-four months (Van Gellekom et al., 2005). Other researchers identify general HRQoL was not affected at any follow-up time points in both the short-term and long-term follow-up (Kobuke et al., 2009, Caffo et al., 2006, Namiki et al., 2006b). The different results between these studies could have been confounded by changes/innovations in treatment. Caution is taken in the interpretation of the results because some patients may have viewed BT as a modern treatment option, whereby patients may have believed that BT may avoid some of the well-known side effects of existing treatments; consequently, their optimistic view of BT may have influenced their responses.

Prostate cancer-specific HRQoL was measured using the FACT-P, AUA, IPSS, UCLA-PCI and EORTC-PR25 for men treated by BT. Obstructive and irritative urinary symptoms are reported problematic at one month (Vordermark et al., 2009, Ball et al., 2006), three months (Nguyen et al., 2009, Namiki et al., 2006b), with recovery at twelve months (Vordermark et al., 2009) that is maintained at sixteen months (Pinkawa et al., 2009a), twenty-four months (Guedea et al., 2009, Ash et al., 2007, Buron et al.,

2007, Caffo et al., 2006, Van Gellekom et al., 2005, Soderdahl et al., 2005), thirty-six months (Chen et al., 2008, Caffo et al., 2006) and forty-eight months (Caffo et al., 2006). These data suggest that obstructive and irritative symptoms are experienced in the short-term but improve over time.

Short-term problems with urinary incontinence have been reported at three and six months, with recovery occurring somewhere between six and nine months, and was reported to improve over pre-treatment scores at twelve months (Feigenberg et al., 2005). Other published data identified that at twenty-four months after treatment, 19.7% of men reported that urinary incontinence was worse than at baseline (Buron et al., 2007). The reports of urinary incontinence recovery are contradictory and inconsistent. Buron's study participants had substantial co-morbidities (2007), whereas Feigenberg's study participants did not have co-morbidities (Feigenberg et al., 2005), which may account for the differing findings of urinary incontinence for BT patients.

Worsening sexual function is demonstrated at one month (Ball et al., 2006) and at six months after BT (Diefenbach and Mohamed, 2007, Ash et al., 2007, Buron et al., 2007, Soderdahl et al., 2005). Sexual function gradually improves at one year (Soderdahl et al., 2005) and two years, (Ash et al., 2007, Buron et al., 2007, Van Gellekom et al., 2005), two and a half years (Nguyen et al., 2009) and at three years (Chen et al., 2008) but is still statistically worse than at pre-treatment scores. However, BT patients have a better sexual function compared to RP and RT patients, consistently over the course from three months to one year post-treatment (Chen et al., 2008, Buron et al., 2007, Soderdahl et al., 2005).

Significant declines in bowel function have been experienced at one month post-BT (Nguyen et al., 2009, Ash et al., 2007, Ball et al., 2006) but fully recovered by one year post-treatment (Caffo et al., 2006, Soderdahl et al., 2005).

Radiotherapy (RT)

Measures used to assess general HRQoL for men treated by RT included the SF-36, FACT-G and the EORTC C30. Prospective longitudinal data demonstrated that physical well-being for men treated by RT declined midway through RT, after RT, at

four weeks, and at two months after treatment (Monga et al., 2005). In addition, emotional and physical problems have been reported to worsen at three months after RT (Namiki et al., 2006c). Improvements in physical and emotional scores consistently improved over baseline scores at six months through to 3 years post-RT (Lips et al., 2009). Other researchers report that global and functional domains of HRQoL did not significantly change from pre-treatment scores over the course of a two-year follow-up (Choo et al., 2007). Individual symptoms (fatigue, pain, insomnia and diarrhoea) have been found to worsen during RT, at two months after RT, through to 2 years after RT (Choo et al., 2007).

Men treated by combination therapy (hormone therapy and RT) for the treatment of locally advanced disease have reported the worse HRQoL compared to RT alone (Stephens et al., 2007). However, combination therapy has been shown to have better tumour control and overall survival for men with locally advanced disease compared to RT alone (Pinkawa et al., 2008).

Prostate cancer-specific HRQoL was measured using the FACT-P, UCLA-PCI and EORTC-PR25 for men treated by RT. Prospective data have identified that only 6% of men report an increase in urinary dysfunction at the end of RT, which later lost statistical significance at two months after treatment (Choo et al., 2007), through to two years after treatment (Namiki et al., 2006c). Longer term follow-up data have identified that 19% of patients report pad usage to manage urinary incontinence at ten years after diagnosis (Fransson et al., 2009a). Data have identified a limit in daily activities caused by urinary symptoms at four, eight and fifteen years compared to age match controls (Fransson et al., 2009a). Age match control studies reiterate similar findings; at approximately 8 years after diagnosis, men experience worse urinary function than age matched controls (Thong et al., 2009). In summary, the reviewed studies suggest that men treated with RT are likely to experience minimal urinary dysfunction after RT, but may experience urinary problems in the long-term.

Bowel dysfunction is commonly reported in men treated by RT. Bowel function significantly worsens during RT, at the end of RT (Namiki et al., 2006c), two months (Pinkawa et al., 2009a), six months (Choo et al., 2007), twelve months (Lev et al., 2009) and at sixteen months after RT, compared to pre-treatment scores (Pinkawa et

al., 2009a). Longer term prospective data have identified that men have been found to experience rectal urgency, diarrhoea and cramp pain at eighteen months, 2 years and at 5 years after diagnosis (Namiki et al., 2009b).

Men treated by combination therapy (hormone therapy and RT) have been found to experience the following symptoms: fatigue, pain, insomnia, diarrhoea, at six, ten, fourteen, eighteen, and twenty-two months after starting treatment. Men treated with combination treatment reported the highest sexual dysfunction and worse physical well-being whilst on hormone therapy (Stephens et al., 2007). Longer follow-up studies have found that urinary and sexual function problems persist at five years after combination treatment (Wahlgren et al., 2007). Recoveries of general HRQoL and sexual functioning have reported at nine months after completing hormone therapy (Wu et al., 2008). However, men treated by combination therapy can experience the poorest urinary, bowel, and sexual function at six weeks and sixteen months after RT, compared to RT alone (Pinkawa et al., 2008). In summary, the trends from the presented findings suggest that men on combination therapy have been found to experience worse HRQoL outcomes, compared to RT alone.

Sexual dysfunction is another major problem for men treated by RT. Sexual function problems are common prior to RT, with approximately 50% of men having experienced sexual dysfunction before RT (Howlett et al., 2010). Interestingly, age matched control studies have identified that at baseline, 22.3% of controls, and 27.6% of patients were unable to obtain an erection (Smith et al., 2009). A different clinical picture emerged after RT, whereby age matched control studies have clarified that sexual function is significantly worse for patients rather than control groups at one, two, and five years post-treatment (Thong et al., 2009). A gradual worsening in sexual function was reported by patients at three, six, twelve, eighteen months (Pinkawa et al., 2009a, Robinson et al., 2009), and at three years post-treatment (Robinson et al., 2009). Evidence suggests sexual function in this patient group does not show any trend of improvement over time.

Watchful waiting (WW)

Evaluating change in general and disease-specific HRQoL over time for the WW patient group is limited. Comparison studies have shown that men under WW scored higher for general HRQoL before treatment, after completion of treatment, and at one year follow-up post-treatment, when compared to men treated with radical prostatectomy, radiotherapy and hormone therapy (Couper et al., 2009). In addition, men under WW have reported better urinary, bowel and sexual function when compared to the other treatments modalities at twelve months (Couper et al., 2009, Fransson et al., 2009a). However, longer follow-up studies acknowledge that physical functioning, insomnia and financial difficulties significantly worsen at four and ten years after diagnosis for WW (Fransson et al., 2009a). At five years post-diagnosis, men under WW have been found to have the poorest HRQoL compared to men receiving radiotherapy (Galbraith et al., 2005). Furthermore, 7% of WW patients have reported wearing pads for urinary incontinence at 10 years after diagnosis (Fransson et al., 2009b). Problems with sexual function have been reported at diagnosis, six months and twelve months (Diefenbach and Mohamed, 2007).

In summary, the evidence suggests that HRQoL is maintained up to the 1st year following diagnosis, but with longer term (4-10 years) negative consequences on general and disease-specific HRQoL. It is unclear how HRQoL is affected at one to three years post-diagnosis. Thus, additional research would be helpful to clarify changes in HRQoL at this time point (1 – 3 years).

Hormone therapy

There were very few studies in this review that assessed changes in HRQoL for men receiving hormone therapy alone. In men diagnosed with metastatic cancer, significant improvements were identified for HRQoL (as measured by the SF-36) for the following scales: pain (at 3 and 12 months), emotional-role, mental well-being (at 6 months), and vitality (at 12 months), when compared to pre-treatment scores (Kato et al., 2007). Urinary function was improved at six and twelve months for some men (Kato et al., 2007). However, sexual dysfunction can be experienced at three, six and twelve months after treatment (Kato et al., 2007). Prostate cancer that has metastasised to the bone carries an increased risk of skeletal related events (i.e. bone fractures and spinal cord compression). Men treated with hormone therapy

who experienced a skeletal-related morbidity have been found to have poor physical well-being and worsening pain, with poorer survival than men without skeletal morbidity treated by hormone therapy (DePuy et al., 2007). From the reviewed publications it is unclear how HRQoL changes after one year and beyond, following hormone therapy. Prospective longitudinal data suggest that men treated with hormone therapy can experience far worse HRQoL scores than men treated with the following: brachytherapy, radical prostatectomy, radiotherapy and watchful waiting (Couper et al., 2009, Gacci et al., 2009, Sanda et al., 2008, Ash et al., 2007).

1.5 Discussion

This review was specifically carried out to address the following questions: 1) what are the predictor variables of HRQoL in men affected by prostate cancer? 2) How does HRQoL change over the prostate cancer journey? Evidence has addressed both research questions; however, it is difficult to produce absolute conclusions about what predicts HRQoL, and how HRQoL changes over time, because of the heterogeneous methods used in the studies included in this review. Broad summaries/trends from the presented evidence are identified for both questions, which was the intention for this review. The volume of HRQoL studies included in this review underscores the recognition among quality of life researchers that the morbidity of this disease is substantial, and men may experience physical and psychological problems for many months, and years, following treatment.

Predictor variables of general and disease-specific HRQoL were demographic, clinical and psychological-social variables. The most *common* predictor variables across all stages of disease were demographics variables (age, ethnicity, marital status, level of education), clinical variables (co-morbidity, Gleason, TNM classification, treatments, and PSA) and psycho-social variables (depression, coping, self-efficacy, perceived stress and social support). This review has identified that psycho-social variables can influence HRQoL, but little (Queenan et al., 2010, Lev et al., 2009, Zavala et al., 2009, Kershaw et al., 2008, Eller et al., 2006, Roberts et al., 2006) psycho-social research was evaluated in this review. Surprisingly, most of the research reviewed has been devoted to physical aspects and side-effects of cancer and treatment, and very little research has assessed emotional distress, and explored the relationship between

coping and social support on HRQoL (Bloch et al., 2007), which is puzzling, given the profound negative effects on HRQoL.

This area would be worthy of further research because the reviewed studies were limited to men with localised disease and, therefore, we currently do not know how the psycho-social variables influence HRQoL for men with locally advanced or metastatic disease. Noteworthy, none of these studies were conducted in the UK. This lack demonstrates the need for additional research that will assess the coping and social support processes that may influence HRQoL in prostate cancer survivors across all stages of disease, namely: localised, locally advanced and metastatic disease. It is anticipated that addressing this knowledge gap will provide useful insights as to how men can be better supported to self-manage their condition and improve HRQoL. In line with this knowledge gap, men living with prostate cancer report that their highest unmet support needs are psychological needs related to emotions and coping (Sanda et al., 2008) and physical needs related to the management of side effects of the disease, associated treatments and on-going issues related to recurrence (Carter et al., 2011, Ream et al., 2008, Boberg et al., 2003).

For the most part, general HRQoL domains recover within the year following treatments. However, it is apparent that specific treatments host different consequences for urinary, bowels and sexual dysfunction. Men treated by surgical approaches often experience poorer outcomes for urinary and sexual dysfunction, compared to brachytherapy, radiotherapy and watchful waiting. Whereas, men treated by radiotherapy or brachytherapy often report poorer bowel function compared to men treated by surgical techniques.

The physical effects of treatments (urinary, bowel and sexual dysfunction) cause profound problems over time for men living with prostate cancer. Sexual dysfunction has been reported to be associated with having the disease and following treatments. The greatest declines in sexual function have been reported within 6 months following treatments, and longer follow-up data at 5 years post treatment, have indicated that sexual function never regained pre-treatment scores. Qualitative studies have described the impact of sexual dysfunction in men affected by prostate

cancer, as a “sense of grief”, “sex life is zero”, and men also described their experiences as not feeling like a “whole man” (Ames et al., 2008, Hedestig et al., 2008). These experiential accounts support extending additional psycho-social research for prostate cancer survivors.

Urinary problems are predictive of general domains of HRQoL (Lev et al., 2009, Eller et al., 2006) and rich experiential accounts have identified some of the issues that men can experience. Qualitative accounts identify that men have had to change their clothes several times daily, and describe their inability of being able to lead a social life due to urinary incontinence, and have voiced worries about the odour from wet pads (Hedestig et al., 2005). This identifies the magnitude of patient experience and the pressing need to research self-management for men with prostate cancer.

One of the most apparent limitations of the HRQoL evidence and a possible source of bias was the lack of data on the usage of post-treatment aids, and modifications to lifestyle that men use to manage their dysfunction, for example: taking medications, changes to lifestyle, and using vacuum devices for impotence. The influences of self-management strategies used by men were not measured in any of the reviewed publications. It is likely that self-management strategies used to alleviate problems would influence HRQoL scores over time. Evidence that identifies the self-management behaviours and the relief of such behaviours would be worthy of further research.

A trend across the reviewed publications acknowledges HRQoL for general and disease-specific domains are at their worst during the first 6 months following treatment. Most baseline reports in longitudinal studies have used pre-treatment, and not pre-diagnosis, to measure comparison in HRQoL over time. It is not possible to undertake pre-diagnosis evaluations due to feasibility issues for the majority of studies in this field. One study however, identified that mental health significantly worsened from pre-diagnosis (assessment at prostate cancer biopsies) to one month after diagnosis (Korfage et al., 2006). Thus, it is likely that pre-treatment scores at baseline are an underestimation of the psychological consequences associated with a diagnosis with prostate cancer. Therefore, assessing the influences of coping and

social support on HRQoL earlier in the cancer trajectory would be helpful to better understand how to support men affected by this disease.

There were a number of methodological limitations that featured across a number of publications. Often the study samples were limited to men who were: white, educated, and married, and as such, they limit the generalisabilty of findings to other minority groups. This was a limitation that featured across a number of publications (Howlett et al., 2010, Parker et al., 2009, Chen et al., 2008, Davison et al., 2007, Daubenmier et al., 2006, Carmack Taylor et al., 2006, Roberts et al., 2006) whereas some researchers did not provide any demographic data (Roeloffzen et al., 2010, Gacci et al., 2009, Pinkawa et al., 2009a, Korfage et al., 2007, Wood et al., 2007, Ash et al., 2007, Prezioso et al., 2007b, Dalkin et al., 2006, Sullivan et al., 2006, Van Gellekom et al., 2005). Bias is possible due to confounding demographic variables and limits the generalisabilty of these findings to wider population groups. Another key limitation was the potential for recruitment and attrition bias in the publications (Roeloffzen et al., 2010, Thong et al., 2009, Couper et al., 2009, Chen et al., 2008, van de Poll-Franse et al., 2008b, Anger et al., 2007, Ash et al., 2007, Galbraith et al., 2005, Van Gellekom et al., 2005, Brar et al., 2005). It is possible that the samples consisted of men in good health that enabled participation in the studies, compared to men with poorer health and who, therefore, were less able to take part. However, the influence of this bias will remain unknown and the findings are treated with caution.

Often the sample sizes in the studies were small, which resulted in underpowered analyses (Fransson et al., 2009a, Zavala et al., 2009, Nguyen et al., 2009, Zhang et al., 2007, Monga et al., 2007, Culos-Reed et al., 2007, Penedo et al., 2007, Carmack Taylor et al., 2006, Jayadevappa et al., 2006, Namiki et al., 2006c). For these studies there is a risk that a type two statistical error was made, for example, believing that HRQoL did not change over time, when in fact HRQoL did. A type one statistical error was possible for one study (Galvao et al., 2010) whereby they performed a large number of statistical comparisons on the data set. Galvao and colleagues did not use a bonferroni adjustment (setting a more stringent alpha level of each comparison); therefore, caution is taken in the interpretation of these findings.

One of the difficulties in interpreting changes in HRQoL over time was that some researchers did not use a baseline HRQoL comparison score, for example, before treatment score. This was a limitation that featured across a small number (10) of studies (Fransson et al., 2009a, Smith et al., 2009, Thong et al., 2009, White et al., 2008, Wood et al., 2007, Zhang et al., 2007, Roberts et al., 2006, Brar et al., 2005, Galbraith et al., 2005, Miller et al., 2005). For these studies the impact of treatment on HRQoL early in the cancer trajectory and beyond is not clear. It would be helpful to aid interpretation that future research in this field used pre-treatment HRQoL scores as a baseline assessment to evaluate changes in HRQoL over time.

One of the challenges in this review was the diverse methodology of the studies included. This review has generated broad summaries and conclusions about what predicts HRQoL and identified how HRQoL changes over the cancer journey. The findings from this review recommend that further research is needed to identify the influence of coping and social support on HRQoL and the self-management behaviours for men affected by prostate cancer.

1.6 Conclusion

This review has provided an opportunity to summarise the trend of predictor variables and recovery in HRQoL, which is useful to clinicians and patients, but has also allowed prioritisation of research needs. This review identified a number of demographic variables (age, ethnicity, marital status, level of education) and clinical variables (co-morbidity, Gleason score, TNM classification, treatments, and PSA) that can predict HRQoL for men with prostate cancer. Yet, despite the abundance of HRQoL literature and widely recognised consequences of having prostate cancer, little is known about how men cope with the aftermath problems associated with this disease, the self-management strategies that men use, or the relationship between coping and social support on HRQoL during the pre-treatment to six month post-treatment trajectory. For the most part, general HRQoL returns to pre-treatment scores by twelve months after treatment, therefore exploring potential predictors sooner in the cancer journey may provide an opportunity to restore HRQoL sooner for men affected by this condition.

In conclusion, this structured review has identified a number of important knowledge gaps around the following issues: the influence of coping and social support on HRQoL, and establishing the self-management behaviours used by men over time. To effectively develop additional research to address these knowledge gaps, it was necessary to conduct two further structured literature reviews to understand the current state of the evidence in relation to: 1) the influence of social support on HRQoL, and 2) the self-management strategies used by men. Chapter two and chapter three are structured reviews of the evidence that were conducted to ensure that this Ph.D. study was developed based upon the best available evidence.

2.0 Social support

2.1 Abstract

Background

Men have reported a lack of support in their pursuit to cope with the problems associated with this disease and its treatments. Little is known about the mechanism effect or the type of social support that links coping to HRQoL. Knowledge in this area can help to identify men who are at risk of impaired HRQoL and provide directions for future research.

Aim

A structured review of empirical literature was undertaken to describe the types of social support that influence HRQoL and the mechanism effect through which social support influences coping and HRQoL.

Methods

The search architecture used the following key words: prostate cancer, prostate carcinoma, health-related quality of life, quality of life, social support, support groups, coping, adjustment, and psycho-social. Databases searched were CINAHL, Medline, PsycInfo, ASSIA, and BNI (from the earliest date available to 2012). A narrative synthesis of the included papers was undertaken.

Results

107 studies were assessed for potential inclusion and 11 publications were included in the review. The literature predominately assessed main effects of perceived social support on HRQoL, and few studies assessed moderation and mediation effects. Perceived social support was frequently assessed, but few studies evaluated the effects of received social support or satisfaction with social support on HRQoL.

Conclusion

Additional research should include a multidimensional inventory of the social support constructs. This will accurately detail how each of the social support constructs influence coping and HRQoL over time. This may provide the basis for the development of appropriately targeted social support interventions for prostate cancer survivors, which are theoretically driven. Future research should be tailored to meet the individual man's social support needs.

2.2 Introduction

Social support for many people is an intuitive term that is used to describe help that is given and received from others in a difficult situation. Research into the role of social support and its relationship to health outcomes has received a lot of attention; however, there are conceptual and methodological problems in the study of social support that are not yet resolved (Cohen et al., 2000; Hupcey, 1998; Callaghan and Morrissey, 1993). These challenges are reflected in the range of existing social support definitions. One of the earliest definitions of social support was by Cobb (1976) and he defined social support as, "the individual belief that one is cared for and loved, esteemed and valued, and belongs to a network of communication and mutual obligations" (p.289). Elsewhere, social support refers to an exchange of resources between at least two people, perceived by the provider, or recipient, to be intended to enhance the well-being of the recipient (Schumaker and Bronwell, 1984). Other investigators have defined social support as, the perceived availability of people whom the individual trusts and who make one feel cared for, and valued, as a person (Thoits, 1986). More recently, social support has been defined as, "the function and quality of social relationships, such as perceived availability of help or support actually received" (Schwarzer et al., 2003, p.3). Suffice to say, there is not a consensus over an agreed definition of social support (Hupcey, 1998), but what can be appreciated from these definitions, is that social support is complex and multi-faceted. The term social support is characterised by looseness and a breadth of measurement approaches to social support that have been previously depicted so clearly by Wortman (1984) and others (Callaghan and Morrissey, 1993; Koasa et al., 1991; Broadhead and Kaplan, 1989; Dunkel-Schetter, 1984).

Social support measures have been operationalised in the following ways: structurally (for example: size of support network, marital status, frequency of social interations, membership in specific environments) or by functionality (for example: emotional, informational, instrumental support) (Cohen et al., 2000; Callaghan and Morrissey, 1993). In addition, functional social support (emotional, informational and instrumental support) can be derived from a variety of sources (for example: partner, sibling, friend, colleague, or doctor, nurse) that can either be received or perceived to be available (Schwarzer et al., 2003; Kobasa et al, 1991).

Within the social support literature, there is an important measurement distinction between perceived social support and received social support (Schwarzer et al., 2003, Cohen et al., 2000). Perceived social support is a construct that is used to describe social support anticipated at a time of need in the future (Procidano and Heller, 1983, Sarason et al., 1983), whereas received social support is based upon retrospective accounts of received social support in the past (Barrera et al., 1981). Moreover, perceived and received social support constructs can be further distinguished by the following types: emotional, informational, and instrumental (Crighton, 2002, Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984). Emotional support generally comes from family and close friends, and is the most commonly recognised form of social support. It includes the provision of empathy, concern, caring, love, and trust (Cohen et al., 2000). Informational support includes advice and suggestions from members of a person's social network that may assist the person to respond to personal or situational demands (Cohen et al., 2000). Instrumental support includes help in the form of money, time, practical assistance, and other explicit interventions on the person's behalf from members of their social network (Helgeson et al., 2006, Helgeson, 2003, Helgeson and Cohen, 1996).

In the previous discussion about how social support has been defined, and what constitutes social support, it is conceptually very important to consider social support as a multidimensional construct, and not as a unitary construct. Thus it is very apparent that social support in healthcare research is complex, and there is a need to reflect upon what social support might mean for men with prostate cancer.

For many patients and family members, a diagnosis of prostate cancer can lead to many ambiguities, such as whether the cancer will recur, whether the cancer will prove fatal, or will it lead to permanent physical problems and disability. For these reasons, and for many others, the experience of prostate cancer is uniquely stressful; and social support has been demonstrated to be beneficial in coping with prostate cancer's associated stressors (Roberts et al., 2006). For men affected by prostate cancer, the meaning of social support might relate to the functional aspects of social support such as: emotional, informational and instrumental support that can be received or perceived from a variety of sources that may include: partner, children, siblings, doctors, nurses, other healthcare professionals, other men with prostate

cancer, friends, colleagues, religious leaders, and members of online peer-support forums. Specifically within the cancer field, patients have described their meaning of functional aspects of social support as: emotional support (love/concern, understanding, reassurance and encouragement), instrumental support (aid or assistance) and informational support (advice, information or a problem-solving nature) that were provided by a variety of sources including: family members, healthcare professionals, friends, and work colleagues (Dunkel-Schetter, 1984). Therefore, for the purpose of this thesis social support is defined as, a multidimensional construct that includes evaluations of perceived, received and satisfaction with the following typologies of support: emotional, information and instrumental support, within a person's social network, as illustrated in figure 2.1.

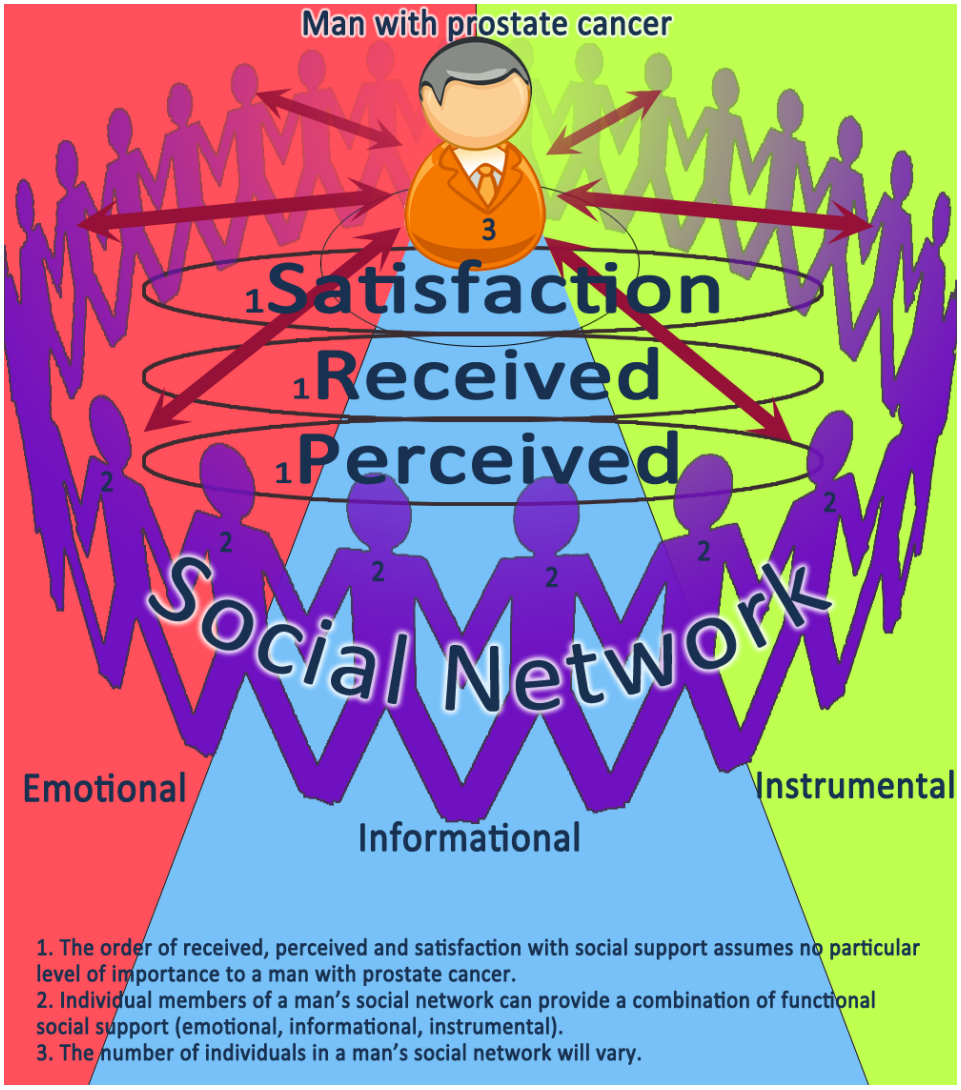


Figure 2.1 Conceptual model of social suppot

The links between social support and health date back to over a century ago. A French Sociologist (Durkheim, 1858-1917) observed that suicides frequently occurred among individuals who had less social ties and weaker social connections. More recently, social support is generally associated with improved physical health and psychological well-being in different patient groups, such as: colorectal cancer (Goldzweig et al., 2009), testicular cancer (Tuinman et al., 2010), breast cancer (Wittenberg et al., 2010, Talley et al., 2010), prostate cancer (Kershaw et al., 2008, Roberts et al., 2006, Kinsinger et al., 2006), heart disease (Janevic et al., 2004), ischemic stroke (Huang et al., 2010), multiple sclerosis (Bambara et al., 2011), mixed cancer groups (Cicero et al., 2009) and patients with metastatic disease (Rodin et al., 2007). Social support has been linked to the reduced incidence of stroke (Maselko et al., 2009), improved mortality for patient with cardiovascular disease (Kravdal and Syse, 2011, Malyutina et al., 2004, Cohen, 1988), and improved mortality for survivors of prostate cancer (Krongrad et al., 1996). Furthermore, social support is linked to improved HRQoL for cancer patients (Helgeson, 2003, Helgeson and Cohen, 1996). The link between social support and improved health outcomes can be explained by the propositions of social support theory.

There are two dominant theoretical frameworks that link social support to improved physical and mental well-being: the *Main Effects Model* (Cohen et al., 2000) and the *Stress Buffering Model* (Cohen and Wills, 1985). According to the main effects model, people with high social support (perceived or received social support) have better physical and mental health compared to those with low social support, regardless of the levels of stress (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984, Cohen and Hoberman, 1983). Social support studies have identified the main effects of social support on HRQoL and are in keeping with the main effects theoretical model (Mehnert et al., 2010, Zhou et al., 2010a, Ah Von et al., 2007, Simoni et al., 2006, Doeglas et al., 1994, Cohen, 1988). The relationship between social support and HRQoL for the main effects model is believed to be linear (Helgeson, 2003), whereas, the *stress buffering hypothesis* states that social support (perceived and received social support resources) is associated with improved physical and mental health only when individuals are exposed to stressful conditions (Christie et al., 2009, Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984, Cohen and Hoberman, 1983). Thus, under conditions of high

stress, social support is believed to act as a buffer (moderator) against the adverse effects of that stressor. The term “buffering” is used because it is believed, according to this theory, that social support lessens the pathogenic effects of a stressor, for example, a cancer diagnosis or living with a chronic illness. In general terms, this type of association, in which the relationship between two variables depends on the level of a third, is known as a moderation effect (Aiken and West, 1991, Cohen and McKay, 1984). The third variable – the stress buffer – is the moderator. Moderation effects are tested statistically by examining the interaction between two predictor variables on the dependent variable. Thus, in order to test the stress buffering hypothesis, one must include an interaction term in statistical analyses (moderation analyses are clearly explained in chapter 4, section 4.7.7 of this thesis).

The stress buffering perspective states that coping performances are enhanced when social support (Cohen et al., 2000) is high, and is very closely related to Lazarus and Folkman’s (1984) theory on stress and coping. The transactional process of stress and coping theory dominates social support research (Lakey and Orehek, 2011) and has been applied to cancer studies (Lehto et al., 2005, Laubmeier et al., 2004, Wonghongkul et al., 2000, Parle and Maguire, 1995, Carver et al., 1993), and details the central importance of social support on improving HRQoL and emotional outcome (see figure 2.2 for social support theoretical model).

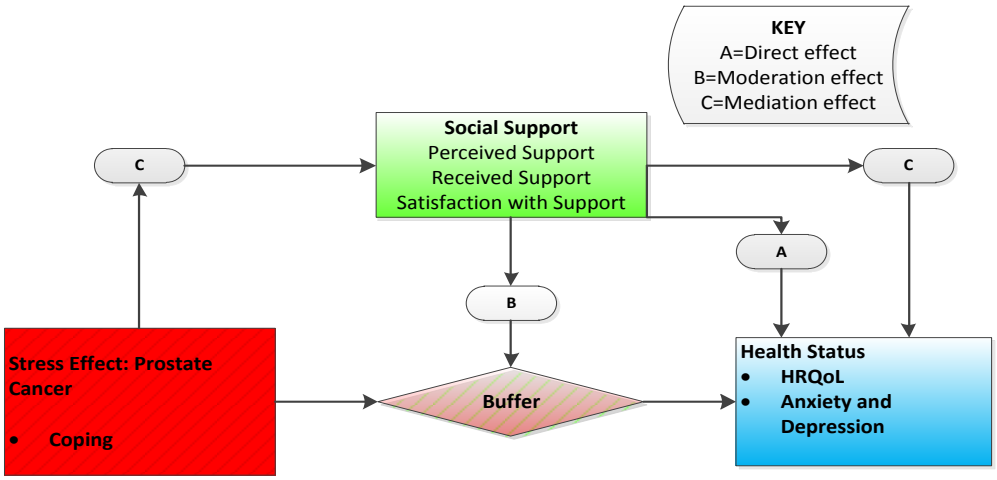


Figure 2.2 Social support theoretical model (Cohen et al., 2000)

In line with Schwarzer's (2003) definition of social support, researchers have developed standardised instruments to measure perceived social support and received social support (see table 2.1).

Table 2.1 Instrument to measures of social support

Study	Name and acronym	Number of items	Reliability	Measurement
(Henderson et al., 1980)	Interview Schedule for Social Interactions (ISSI)	24	0.71	Perceived emotional attachment
(Procidano and Heller, 1983)	Perceived Support from Friends and Family (PSS)	40	0.90	Perceived emotional/informational support
(Sarason et al., 1983)	Social Support Questionnaire (SSQ)	27	(Family) 0.88 (Friends 0.97	Perceived emotional support
(Cohen and McKay, 1984)	Interpersonal Support Evaluation List (ISEL)	40	Scales 0.70 to 0.90	Perceived emotional, instrumental, companionship support
(Power et al., 1988)	Significant Other Scale (SOS)	56	Scales 0.73 to 0.83	Perceived emotional and instrumental support
(Barrera et al., 1981)	Inventory of Socially Supportive Behaviours (ISSB)	40	>0.90 for all scales	Received emotional, informational, instrumental, companionship support
(Dunkel-Schetter et al., 1987)	UCLA Social Support Interview (UCLA SSI)	70	Reliability not reported	Received emotional, informational, instrumental support
	Cancer-specific measures			
(Schulz and Schwarzer,	Berlin Social Support Scale	45	Scales 0.63 to 0.83	Perceived, received

2003) (Bottomley, 1995)	(BSSS) Bottomley Cancer Social Support Scale (BCSSS)	 9	 Scales 0.76 to 0.77	emotional, informational, instrumental and satisfaction of support Perceived emotional and confident support

Many of the general measures of social support are inappropriate for use in cancer because reliability and validity have not been established for cancer patients. The content of the social support measures maybe relevant only to general populations and not for people affected by cancer. There are only two instruments (Berlin Social Support Scale and Bottomley Cancer Social Support Scale) that have been developed to evaluate cancer-specific social support. Both cancer-specific measures are reliable and valid, but the Berlin Social Support Scale would be the strongest candidate instrument for future research for a number of important reasons. The Berlin Social Support Scale (BSSS) is a multi-dimensional inventory of the social support constructs that includes received, perceived and satisfaction with social support that may refine the propositions of existing social support theory. Furthermore, the validity and reliability of the BSSS has been previously established for men affected by prostate cancer (Scholz et al., 2008) whereas, the Bottomley Social Support Scale has not previously been used in prostate cancer patients.

Coping is also central to the propositions of social support theory. The coping and stress process and are best described as a transactional process that depends on the availability of support (internal/external resources) and personality assets (Cooper and Watson, 1991) of the person. According to the transactional process of stress and coping, social support represents one resource factor, among others, that influences cognitive appraisal of stressful encounters. Coping, then, is a result of cognitive appraisal, and the more social support that is available, positive coping efforts are believed to be better facilitated (Lakey and Orehek, 2011). An association between coping and HRQoL for men affected by prostate cancer has been identified (Zhou et al., 2010a, Couper et al., 2010, Ahmad et al., 2005).

Specifically, a diagnosis of prostate cancer can trigger a number of life-altering decisions that can induce stress, for example: diagnosis, treatment-making decisions, after-effects of treatment, and financial difficulties. Coping is always related to the specific demands (stressors) of a given situation and how individuals appraise these tasks as taxing, or exceeding their resources. In this context, men can experience severe and enduring decrements in HRQoL (as identified in chapter 1) and social support might help men in their pursuit to cope with the profound physical and psychological sequelae (Department of Health Macmillan Cancer Support & NHS Improvement, 2010, Boehmer and Babayan, 2005, Boberg et al., 2003). For the purpose of this thesis, living with prostate cancer is conceptualised as the stressor.

Coping can generally be defined as cognitive and/or behavioural attempts to manage situations that are appraised as stressful to an individual (Roesch et al., 2005). For the purpose of this thesis, coping is defined as "constantly changing cognitive and behavioural efforts to manage specific external or internal demands that are appraised as taxing or exceeding the resources of a person" (Lazarus and Folkman, 1984, p.141). Coping is one link in a stress process, contingent on appraisal, which involves judging the personal significance of a stressful encounter. The assessment of coping is a description of the behaviours and cognitions of a person dealing with a stressful encounter. Given the dynamic nature and complexity of coping, a range of standardised measures have been developed to measure different levels of specificity of coping and these include: dispositional coping styles (Carver et al., 1989), situation specific coping (Folkman and Lazarus, 1988, McCrae, 1984, Bilings and Moos, 1984, Bilings and Moos, 1981) and cancer-specific assessment of coping (Watson et al., 1988a). This is not an extensive list of coping instruments, but illustrates the different levels of assessment of coping. Many of the measures of coping are inappropriate for use in prostate cancer patients because reliability and validity have not been established in this patient group and the content may be more relevant to general populations, and not for people affected by cancer. In order to understand coping, it is necessary to examine coping in the context of the problems with which people with cancer are affected.

In particular, the adjustment to cancer has been defined as the cognitive and behavioural responses that patients make to their diagnosis of cancer (Watson and

Homewood, 2008, Greer et al., 1989, Watson et al., 1988a). Watson and colleagues in 1984 developed a standardised measure (Mental Adjustment to Cancer [MAC] Scale) to assess patients' coping styles in relation to their cancer. This instrument evaluates five dimensions of coping styles: fighting spirit, helplessness or hopelessness, anxious preoccupation, fatalism and avoidance. This instrument has demonstrated reliability and validity in breast cancer (Carlsson et al., 2005, Inoue et al., 2003, Okano et al., 2001, Osborne et al., 1999, Schnoll et al., 1998), lung cancer (Mulcare et al., 2011, Uchitomi et al., 2003), laryngeal cancer (Johansson et al., 2011) and prostate cancer (Couper et al., 2010, Shields et al., 2004). Therefore, the MAC Scale is considered the strongest candidate instrument for additional research in this area.

Researchers using standardised instruments that provide an assessment of coping, including the MAC Scale, imply that people can be characterised by particular styles of coping, and that they continue to apply the same kind of coping strategies over time. This dispositional implication helps to reduce the complexity of coping assessment, but the uniqueness of situational-specific coping responses for people affected by cancer are not accurately measured, if at all. One approach that may adequately capture coping responses over time could be case-based time series design methodologies to capture daily changing in coping cognitions and behaviours (Borckardt et al., 2008). Extending the field using real time data collection methodologies would be a worthwhile step to understand the individual man's coping experiences as they unfold over time.

In the context of prostate cancer, little evidence details how men cope or has identified the relationship that links social support and coping to HRQoL (Bloch et al., 2007, Roesch et al., 2005). Social support has recently been identified as an important target for potential psycho-social work aimed at improving HRQoL for men living with and beyond prostate cancer (Zhou et al., 2010a). To advance the field further there is a need to establish the current evidence base to identify the mechanism effect that links social support to HRQoL for prostate cancer survivors. The purpose of this structured review was to describe the type of social support that can influence HRQoL and to identify the mechanism effect through which

social support influences HRQoL for men affected by prostate cancer. Two research questions were used to guide this structured review:

2.3 Review questions:

1) What types of social support (perceived, received and satisfaction) influence HRQoL for men living with prostate cancer?
2) What are the mechanism (main/moderation/mediation) effects of social support on HRQoL for men with prostate cancer?

2.4 Methods

A review of qualitative and quantitative research was generated to provide a broad overview of existing knowledge in this field (Webb and Roe, 2007). Guidance provided by the Centre for Reviews and Dissemination (2008) was used to promote rigour and transparency for the review methodology. The steps involved included:

1) Formulation of the research questions
2) Developing review protocol
3) Searching and identifying the research evidence
4) Rating the studies for inclusion based on inclusion/exclusion criteria
5) Data extraction using a pro forma sheet
6) Quality assessment
7) Results synthesis

2.4.1 Searching and identifying the evidence

The search architecture used the following key words: prostate cancer, prostate carcinoma, health-related quality of life, quality of life, social support, support groups, coping, adjustment, and psycho-social. Databases searched were CINAHL, Medline, PsycInfo, ASSIA, and BNI, and key words were mapped to each electronic database using the appropriate MeSH (medical subject heading) term, or used free search terms around prostate cancer and social support. Databases were searched from earliest date available using truncation, wildcards and Boolean logic. Literature was searched from the earliest date available to ensure all relevant hits were identified. Sourcing grey literature has been recognised as problematic (Webb and Roe, 2007) and, therefore, grey literature searches were performed in Index to

Theses, Google Scholar, and Google. All of the publications were managed using the software package Endnote X4.

2.4.2 Inclusion and exclusion of studies

Level of evidence was categorised by the Department of Health in the National Service Framework (2001) (see table 2.2). This framework was used because it has been applied to peer-reviewed and non-peer reviewed research (Anderson et al., 2004).

Table 2.2 Evidence categories used by the Department of Health in the National Service Framework.

Typologies of supporting evidence
A1 Systematic reviews, which include at least one randomized control trial (RCT), e.g. systematic reviews from Cochrane. A2 Other systematic and high quality reviews. B1 Individual RCTs. B2 Individual non-randomized, experimental/interventional studies. B3 Individual well-designed non-experimental studies, controlling statistically if appropriate. Includes case control, longitudinal, cohort, matched pairs or cross-sectional random sample methodologies, and well-designed qualitative studies, well-designed analytical studies including secondary analysis. C1 Descriptive and other research or evaluations not in B (e.g. convenience samples). C2 Case studies and examples of good practice. D Summary review articles and discussions of relevant literature and conference proceedings not otherwise classified.

Based on this typology, this review included research at the level of C1-A1 for inclusion. This review excluded studies at the level of evidence D-C2. See table 2.3 for summary of inclusion criteria and rationale. For the purposes of this review and thesis a social support intervention is broadly defined as, an intervention that includes any of the following social support typologies: informational, emotional or instrumental support.

Table 2.3 Inclusion criteria

Criteria	Rationale
Levels of evidence C1-A1	Allowed for the inclusion of quantitative and qualitative methods, identifying the levels of evidence by study design.
Does this title/abstract indicate how social support (types) can influence HRQoL for men with prostate cancer?	This is the 1st key focus of the review; to establish which types of social support influence HRQoL for men with prostate cancer.
Does this title/abstract identify the mechanism by which social support operates in relation to HRQoL for men with prostate cancer? (The publications had to address at minimum, one of the above questions to be considered for inclusion)	This is the 2nd key focus of the review; to establish the mechanism through which social support operates in influencing HRQoL.

English text only	Budget constraints and the costs involved for translation
Grey Literature	To try and minimise the risk of publication bias
Prostate cancer patients only	This is the primary context of the review; therefore other cancer sites would be excluded.
Quantitiative studies must include a measure social support	To clearly identify the mechanism effect of social support
No geographical limitation	To capture a broad range of social support evidence worldwide.

The publications (titles and abstracts) found by the search strategy were reviewed independently by 3 members of the research team (2 of the researcher's Ph.D. supervisors and the researcher) using a pro forma checklist to make decisions to include or not include studies, based on the criteria presented in Table 2.3. Publications meeting the inclusion criteria were retrieved in full text.

2.4.3 Quality assessment

Two quality assessment appraisal tools were used; one quantitative appraisal tool and one qualitative appraisal tool (Shaw et al., 2009). The quality assessment appraisal tools enabled a plethora of methodologies to be evaluated within this structured review.

2.4.4 Data extraction

Key information from the studies was extracted using narrative data extraction sheets. Data extraction was developed based on recommendations from Cochrane Guidelines (2009) and guided by the review questions (see table 2.4).

Table 2.4 Data extraction

- Unique reference number (for reviewers reference)
- Authors
- Year of publication
- Country
- Overall aim of the study
- Participants' characteristics (age, race, education, cancer stage, cancer treatments)
- Number of patients approached, and the number of patients consented (identify the possibility of selection bias)
- Methods – study design, time points for data collection, measures (variables in the study), intervention details, method of randomization, and participants' attrition rates.
- Overall findings and conclusions
- Limitations

2.4.5 Evidence synthesis

The review used a narrative synthesis and tabulation of primary research studies to generate broad findings and conclusions. More specifically, the review undertook the following steps: *data reduction* (sub-group classification based on levels of evidence and the review questions), *data comparison* (iterative process of making comparisons and identifying relationships) and finally, *conclusion and verification* (checked primary data sources for accuracy and confirmability) (Whittemore, 2005). This process has been applied to several structured literature reviews, including cancer (Flinkman et al., 2010, Da Silva et al., 2010, Kennedy et al., 2008).

2.5 Findings - overview of studies

Of the 107 publications retrieved from the search, 74 were excluded following the application of the inclusion/exclusion criteria (see figure 2.2). This left 33 publications reviewed in full, and 22 articles were excluded (Queenan et al., 2010, Galvao et al., 2010, Christie et al., 2009, Parker et al., 2009, Penedo et al., 2007, Monga et al., 2007, Culos-Reed et al., 2007, Northouse et al., 2007b, Berglund et al., 2007, Siegel et al., 2007, Luszczynska et al., 2007a, Voerman et al., 2007, Jones et al., 2006, Penedo et al., 2006, Kinsinger et al., 2006, Steginga et al., 2005, Eton et al., 2004, Weber et al., 2004, Lepore et al., 2003, Robinson et al., 1999b, Krongrad et al., 1996) because they did not meet inclusion criteria (see figure 2.2). This left 11 publications which fully met the inclusion criteria: two intervention studies, six prospective longitudinal surveys and three cross-sectional surveys. An inter-rater reliability analysis using the Kappa statistic was performed to determine consistency among reviewers using the inclusion/exclusion proforma. The results demonstrate almost perfect agreement, Kappa= 0.922, $p<0.001$ (Viera and Garrette, 2005).

Eleven quantitative designs and no qualitative publications were included in the review. This is a relatively small number of publications and indicates the lack of research in this field. The studies were mainly conducted in America and European countries, but none of the studies were conducted in the UK. Samples sizes varied from N=30 to N=511 with a total sample N=1847 across all of the publications. Based on the Departments of Health (2001) typologies of evidence, most of the publications were classified as B2 (interventional studies), B3 (longitudinal surveys) and C1 (cross-sectional convenience samples).

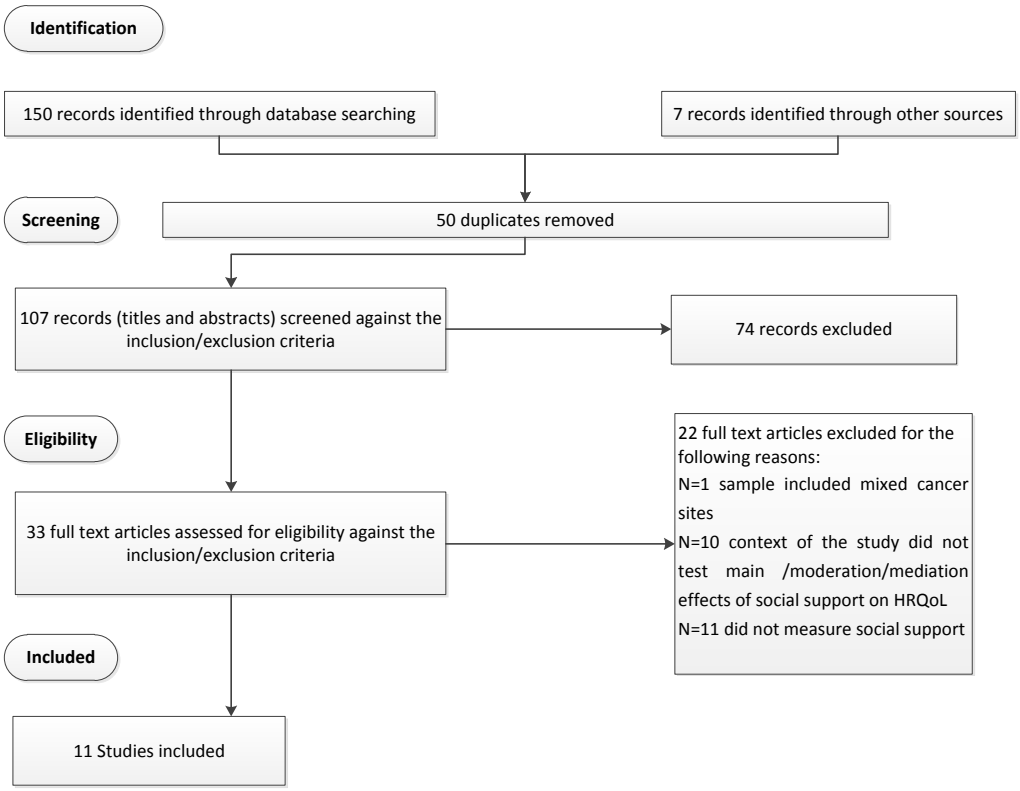


Figure 2.3 PRISMA: Flow of information through the different phases of the social support review (Moher, 2009)

All of the publications included in this review reported findings pertinent to understanding the main effects of social support on HRQoL. Only 4 publications (Zhou et al., 2010a, Scholz et al., 2008, Carmack Taylor et al., 2006, Roberts et al., 2006) reported findings relevant to understanding the moderation and mediating effects of social support on HRQoL. Table 2.5 provides an overview of the included publications and full data extraction is available in appendix 2.1.

Table 2.5 Overview of studies included in this review

Reference	Country	Design	Sample and trajectory	Social support measurement	Main effect tested	Moderation/mediation effect tested	Results
(Carmack Taylor et al., 2007, Carmack Taylor et al., 2006)	USA	Intervention study - 3 groups: 1) lifestyle programme, 2) educational support, 3) control	N=134 men receiving hormone therapy continually for 1 year (mean time on HT 32.7 months). Time since diagnosis not reported.	Perceived social support (Interpersonal Support Evaluation Checklist) (Cohen and Hoberman, 1983)	Yes	Yes	No significant differences were found between the study conditions on HRQoL. Moderation effect – participation in a group benefited those with greater anxiety and depression or with the least social support compared to the control.
(Weber et al., 2004)	USA	Intervention study – 2 groups: 1) dyadic peer supportive partners, 2) control	N=30 men treated by laparoscopic radical prostatectomy, 6 weeks post-surgery	Received social support (Inventory of Social Support) (Barrera et al., 1981)	Yes	No	No significant changes in social support over time. No significant differences were found between the study conditions on HRQoL.
(Scholz et al., 2008)	Germany	Prospective longitudinal survey	N=77 men treated with laparoscopic radical prostatectomy, 2 weeks and 6 months after surgery	Received and provided social support (Berlin Social Support Scale)(Schulz and Schwarzer, 2003)	Yes	Yes	No main effects on HRQoL. Participants with low HRQoL (T1) was associated with high HRQoL (T2) when they had more social support (T1).
(Roberts et al., 2006)	USA	Prospective longitudinal survey	N=93 men with localised disease, various treatment modalities. Time since treatment range 7-120, mean 46.7 days, SD not reported.	Perceived social support (Social Provisions Scale) (Curtona and Russell, 1987)	Yes	Yes	Social support was significantly related to HRQoL. Coping mediated the relationship between social support and HRQoL.
(Kershaw et al., 2008)	USA	Prospective longitudinal survey	N=134 men with various treatments and stages of disease. Time since diagnosis not reported.	Perceived social support (Personal Resource Questionnaire) (Brandt and Weinert, 1981)	Yes	No	Social support did not have a main effect with HRQoL. Social support had a significant relationship with coping. Coping and appraisal predicted HRQoL
(Andel et al., 2004)	Netherlands	Prospective longitudinal survey	N=138 men treated with radical prostatectomy and external beam radiotherapy for localised and locally advanced disease. Before treatment and 1 year follow-up	Perceived social support (Social Support Questionnaire) (Sarason et al., 1983)	Yes	No	Social support and coping were associated with HRQoL.

Reference	Country	Design	Sample and trajectory	Social support measurement	Main effect tested	Moderation /mediation effect tested	Results
(Visser et al., 2003)	Amsterdam	Prospective longitudinal survey	N=23 men with prostate cancer (clinical variables not reported) and N=37 men with benign prostatic hyperplasia. Before diagnosis and 3 months follow-up)	Perceived social support (Social Support Questionnaire) (Sarason et al., 1983)	Yes	No	Social support and coping was related to HRQoL.
(Zhou et al., 2010a, Zhou et al., 2010b)	USA	Prospective longitudinal survey	N=180 men with localised disease treated with radical prostatectomy and external beam radiotherapy. 10.6 months (SD 4.8) since treatment, 15.4 (SD 6.2) months since diagnosis.	Perceived social support (Social Support Questionnaire) (Sarason et al., 1983)	Yes	Yes	Social support was a main predictor of HRQoL. The relationship between Social support and HRQoL was partially mediated by perceived stress. Social support and HRQoL was partially mediated by coping.
(Poole et al., 2001)	Canada	Cross-sectional survey	N=240 men with different treatment modalities, stages not reported. 27 (SD 34.7) months since diagnosis.	Perceived social support (Social Support Questionnaire) (Sarason et al., 1983)	Yes	No	No difference between attenders (support group) and non-attenders for coping, HRQoL or social support scores.
(Rondorf-Klym and Colling, 2003)	USA	Cross-sectional survey	N=88 men treated with radical prostatectomy for localised disease. 12-24 months after surgery	Perceived social support (Personal Resource Questionnaire) (Brandt and Weinert, 1981)	Yes	No	Social support had a main effect on HRQoL.
(Mehnert et al., 2010)	Germany	Cross-sectional survey	N=511 men treated with radical prostatectomy. 27 month (mean) since surgery.	Perceived social support (Illness Specific Social Support) (Revenson et al., 1991)	Yes	No	Social support had a main effect on HRQoL.

2.5.1 Findings

Interventions (two studies)

Two interventions studies (Carmack Taylor et al., 2007, Weber et al., 2004) were reviewed. One study (Carmack Taylor et al., 2007) used a lifestyle/educational intervention and the other study (Weber et al., 2004) used peer support as the intervention component to improve HRQoL. Carmack Taylor and colleagues developed three study conditions for men undergoing hormone therapy: 1) lifestyle programme, 2) education support, and 3) standard care group. The lifestyle programme encouraged men to take regular exercise, set goals, supported men to overcome barriers, and educated men on caloric intake and exercise. The educational support group was based on group discussion on prostate cancer topics such as: diet, exercise, side-effects of hormone therapy, and sexuality. The control condition was standard care, although there was no description of what standard care was. No statistically significant differences in HRQoL (as measured by SF-36) scores were found between the 3 groups from baseline (men on hormone therapy for 32.7 months, mean time) and at six and twelve months. The researchers did not perform mediation analyses of social support and physical activity because HRQoL did not change over time, which was the dependent variable of interest. Furthermore, perceived social support did not significantly change at six or twelve months. However, at 6 months, participation in a group (lifestyle or educational support) only benefited men who had the worst distress (anxiety and depression) or the lowest perceived social support scores at baseline, compared to the control group (Carmack Taylor et al., 2007). This result indicates a moderating (buffering) effect because social support was most helpful to men when they experienced high levels of stress. This moderating effect is linked to the stress buffering model, in that social support is only helpful to individuals when under high levels of stress.

These finding should be viewed with caution as there are a number of limitations to Carmack Taylor's study. In total, 948 men were invited to take part in the study, but only N=134 consented to take part, which is a 14.1% consent rate. Differences between men who consented to take part and men who did not consent were not

assessed. Therefore, recruitment bias is possible and the findings may not be generalisable to the wider population. This study was also underpowered and was at risk of a type two statistical error.

The second intervention study included in this review (Weber et al., 2004) tested the effects of a dyadic peer support (one-to-one) in a population (N= 30) of men treated by radical prostatectomy. The supportive partners (N=10) were long-term survivors of prostate cancer (9 white, 1 black), with a mean age 68.2 years, and a stable PSA for one year prior to the study. The supportive partners underwent a 2-hour training session, but the researchers did not specify who delivered the training. Each dyad met eight times during an eight-week period in a relaxed atmosphere where a private conversation could take place about problems that may have been encountered. Overall, no statistically significant intervention effect was found on HRQoL, and no difference was found for received social support scores at four and eight weeks post intervention. The findings from this study (Weber et al., 2004) did not identify a main effect of social support and moderation/mediation effects were not tested. The findings from this study are difficult to generalise to the wider prostate cancer population because the results are limited to men who were mostly white, married and educated, and all treated by radical prostatectomy. This intervention study (similar to Carmack Taylor) had a high consent refusal rate (70%) (Weber et al., 2004). No statistical comparisons were reported to check for recruitment bias between the men who had consented to the study and those men who did not consent. Caution is taken in the interpretation of the results as medical or demographic variables may have biased recruitment. Participant attrition was not identified in Weber's study and 16% of participant attrition was reported in Carmack Taylor's study. Carmack Taylor did not identify the form of analysis that they implemented, for example, completed cases versus intention to treat (Schulz et al., 2010). Consequently, bias maybe possible if the participants lost from the study were different from those included in the results, but this remains unknown.

There are two common findings across both intervention studies reviewed: 1) no overall intervention effect on improving HRQoL, and 2) the high refusal rate of participation in the studies. There are a number of possible explanations for the

similarities between the findings. One explanation to account for no intervention effect may be due to aggregate group level statistics. Thus, the interventions may have been effective in improving HRQoL for some individuals, but because of the average group statistics used; such an effect was not detected. This seems a likely explanation because Carmack-Taylor and colleagues demonstrated, based on secondary moderation analyses, that their intervention was only beneficial for men in distress or with limited social support at baseline (Carmack Taylor et al., 2007). Targeting future interventions to select participants who are in most need may be helpful to tailor interventions to the individual man's needs (Cockle-Hearne and Faithfull, 2010). A further point for consideration was the low consent rates across both intervention studies. Noteworthy, both studies did not report patient involvement in the intervention design, and therefore may not have addressed men's preferences of the intervention or the needs of these men. Thus, the studies do not reflect the Medical Research Council's (Craig et al., 2008) framework for complex interventions because of the lack of patient involvement in the development of the interventions.

In summary, the findings from (Weber et al., 2004) did not identify a main effect of received social support, whereas Carmack Taylor identified at six months post-treatment, participation in a group (lifestyle or educational support) only benefited men who had the worst distress (anxiety and depression) or the lowest perceived social support scores at baseline, compared to the control group (Carmack Taylor et al., 2007). Carmack Taylor's result indicates a moderating (buffering) effect because social support was helpful to men when they experienced high levels of stress.

Cross-sectional and longitudinal surveys (nine studies)

All of the reviewed studies used standardised instruments to measure social support. Eight of the nine studies measured perceived social support and one study measured received social support. Perceived social support was found to have a main effect on HRQoL for a number of studies (Zhou et al., 2010a, Mehnert et al., 2010, Roberts et al., 2006, Van Andel et al., 2003, Visser et al., 2003, Rondorf-Klym and Colling, 2003). These studies provide support for the main effects theoretical model (Cohen et al., 2000), in that perceived social support had a positive effect on improving HRQoL for

prostate cancer survivors. Received social support provision was measured in one study only (Scholz et al., 2008) but it did not have a main effect with HRQoL. Thus the construct of perceived social support appears to be more strongly related to HRQoL compared to received social support on HRQoL, and this has been reported elsewhere (Helgeson et al., 2006). However, caution is given in the interpretation of some of the findings due to some methodological limitations. A common limitation to three studies (Kershaw et al., 2008, Roberts et al., 2006, Rondorf-Klym and Colling, 2003) was that the study samples were not representative of the prostate cancer population and, therefore, this limited the generalisabilty of the findings. Specifically, minority groups were under-represented in the study samples, for example, men of different ethnic groups and of a lower educational level. A further difficulty in the interpretation of the findings from three studies (Zhou et al., 2010a, Kershaw et al., 2008, Roberts et al., 2006) was that baseline social support and HRQoL was not assessed before treatment. Consequently, it is difficult to identify change over time and to understand the influences of coping and social support on HRQoL at diagnosis, which can be a particularly difficult and traumatic time for men.

Only four publications (Zhou et al., 2010b, Scholz et al., 2008, Carmack Taylor et al., 2007, Roberts et al., 2006) illustrated moderation and mediation effects through which social support operated with HRQoL. Carmack Taylor conducted a moderation analysis and identified that participation in a group benefited participants with the greatest distress (anxiety and depression), or with least social support, compared to the control group (see appendix 2.1 for full details of the intervention). Although this study demonstrated findings that may be broadly related to the buffering hypothesis, the limitation with these data is that they do not expand knowledge and understanding about how coping and social support are linked to HRQoL. A further study (Scholz et al., 2008) found a similar moderation effect. Scholz and colleagues performed simple slope analysis (Aiken and West, 1991) based on 1 standard deviation (SD) above and 1 SD below the mean values for the moderator variable (received social support). Findings demonstrated that low HRQoL (at time 1) was associated with a higher HRQoL (at time 2), when social support is high (at time 1), whereas, when HRQoL is high (at time 1), social support had little influence on improving HRQoL (at time 2). Scholz's findings have similar interpretation to the

buffering hypothesis because this theory states that social support is only helpful under conditions of high stress (Cohen et al., 2000). Both studies (Scholz et al., 2008, Carmack Taylor et al., 2007) have a similar interpretation to the buffering hypothesis in that social support is only helpful under conditions of high stress (Cohen et al., 2000).

Other researchers (Roberts et al., 2006) examined how perceived social support and coping influenced HRQoL in a population (N=89) of men with localised disease (mixed treatment modality). The findings identified the main effects of social support and coping (positive coping) on HRQoL, but also mediation was demonstrated. Data identify that social support (Time 1, several months after treatment) and HRQoL (Time 2, 3 months follow-up) were partially mediated by positive coping (Time 1) (Sobels test, Z=2.84, p=.0.004). These data suggest that perceived social support was related to HRQoL because of improved coping. However, Roberts did not test buffering (moderation) effects of social support and, therefore, these data provide support for the main effects model, but not for the stress buffering model. This study has provided some evidence of a causal pathway linking social support and coping to HRQoL. There are a few limitations to Robert's study that should be noted. The researchers did not have adequate representation from individuals from minority groups and of lower socio-economic status; predominantly the study sample was white, married, educated and of a higher socio-economic status. Furthermore, the study was limited to men with localised disease, and therefore the influences of coping and social support on HRQoL for men with more aggressive cancer (locally advanced and metastatic disease) remains unknown. Finally, baseline evaluations were assessed following completion of initial treatment; therefore these data do not detail the mechanism of coping and social support on HRQoL during critical periods surrounding diagnosis and follow-up testing, for example, at six months follow-up.

More recently, researchers assessed the influence of perceived social support and coping on HRQoL for men with localised prostate cancer (Zhou et al., 2010b). Data demonstrated a main effect of perceived social support ($\beta=0.15$, $p<0.01$) at baseline (approx 10 months post-treatment) on HRQoL at 2 year follow-up. Furthermore, mediation analyses were performed to examine whether positive coping mediated

the relationship between perceived social support and HRQoL. Data identified that the relationship between social support and HRQoL was partially mediated by positive coping (Sobels test, Z= -2.29, p<.05). These findings suggest that social support is related to HRQoL because of positive coping efforts. In addition, perceived social support and positive coping were longitudinal predictors of HRQoL. This study targeted post-treatment adjustment and, therefore, the researchers did not assess the availability of social support and coping styles before treatment. These data cannot determine the extent to which having adequate social support and coping styles during the early cancer trajectory may relate to long-term adjustment in this population. This study did not examine the relationship between social support and negative coping efforts and thus, additional work would enrich understanding of the influence of social support and coping (positive and negative) on HRQoL.

In summary, main effects of perceived social support on HRQoL have been identified across many of the reviewed studies. Received social support did not have a main effect on HRQoL but operated through moderation effects. Finally, social support was significantly related to HRQoL because of positive coping efforts.

2.6 Discussion

In this structured review the types and effects of social support on influencing HRQoL for men with prostate cancer were considered. The importance of social support as a resource for people affected by cancer is not a new concept, but specifically, prostate cancer survivors have reported a lack of support for their unmet physical and psychological problems (Ream et al., 2008, Boberg et al., 2003, Lintz et al., 2003). HRQoL is likely to be affected by the psychological and social factors that unfold over time as men manage, learn from, and adjust to the changes caused by prostate cancer and its associated treatments (Roberts et al., 2006). It is likely that social support needs will also change over time. Understanding the mechanism effect of how coping and social support operate on HRQoL over time can help to identify men who are at high risk and suggest directions for intervention. This concept has recently been supported elsewhere (Roesch et al., 2005).

This review has illustrated a pressing need for additional work to understand the influences of psycho-social factors on men's HRQoL. To this end, current health care policy in the UK (Department of Health Macmillan Cancer Support & NHS Improvement, 2010, The Scottish Government, 2008, Scottish Executive, 2004) has acknowledged the need for tailored support for individuals with cancer and details the need for additional research in this field. This review has provided evidence which has addressed the two review questions, but this field is still in its infancy, is under-developed, and under-researched. In relation to the first research question, the reviewed data have identified that perceived social support and received social support has been found to influence HRQoL for prostate cancer survivors. None of the reviewed studies evaluated the influence of satisfaction with social support on HRQoL. None of the studies identified how emotional, informational and instrumental facets of support provision may affect HRQoL or change over time. Data which detail changes in social support (informational, emotional, instrumental) provision for men throughout the prostate cancer journey would provide useful insights into how men can be better supported.

Within the general cancer social support literature, there is evidence to suggest that informational, instrumental and emotional support are positive resources for adjustment to cancer, but some cancer patients have voiced negative/unhelpful experiences of social support. For people affected by cancer sources of unhelpful social support have been identified from: family, healthcare professionals, friends, work colleagues, and strangers (Dunkel-Schetter, 1984). Examples of unhelpful support have been described as doctors appearing unfeeling towards a patient's emotions, or when clinical care has been provided without appropriate informational or emotional support (Dunkel-Schetter, 1984). Other areas of unhelpful social support include sources of informational support. There is some evidence to suggest that when information is provided by family members it can be viewed as unhelpful; whereas, when informational support has been provided by healthcare professionals it is generally viewed as more helpful (Dunkel-Schetter, 1984; Wortman, 1984). For people affected by cancer positive experiences of social support have been described as the expression of feelings (emotional support) "being with me when I needed somebody", or the appropriate provision of informational support "he spelled it right

out for me, he told me it might not be malignant or it might be, and he told me the different types of treatment I might have … not in medical terms, but in lay terms you could understand" (Dunkel-Schetter, 1984 p.85). By drawing on the broader social support literature in cancer, it has clearly demonstrated that not all provisions of social support for people affected by cancer are viewed as positive or helpful. This review has identified a dearth of prostate cancer research, whereby little is known about the relationship between informational, instrumental and emotional support on HRQoL. As a recommendation for future social support research in prostate cancer, researchers should evaluate the following typologies of social support: informational, emotional, and instrumental support to inform the existing evidence-base.

The findings which addressed the second review question (what are the mechanism [main/moderation/mediation] effects of social support on HRQoL?) identified that social support can influence coping and HRQoL through main, moderating, and mediating effects. Specifically, several studies (Mehnert et al., 2010, Roberts et al., 2006, Visser et al., 2003, Rondorf-Klym and Colling, 2003) provided support for the main effects model, thus identifying the benefits of perceived social support on HRQoL. The provision of received social support did not have any main effects with HRQoL, but operated through moderation analysis. Several publications provided support for the stress buffering model (Scholz et al., 2008, Carmack Taylor et al., 2007), although for one (Carmack Taylor et al., 2007), this was not the implicit aim of the study.

A major limitation that featured across the majority of the studies was the absence of a multi-dimensional inventory of the social support constructs, namely: perceived social support, received social support and satisfaction with social support, within the context of each individual study. Nine of the eleven studies measured perceived social support only, and two studies measured received social support. Therefore, existing evidence is largely restricted to the assessment of perceived social support. Perceived social support has been found to reflect more of personality disposition (Sarason et al., 1986) rather than actual social support transitions, and thus intervention design can be difficult to design for personality-level constructs.

To overcome this constraint, additional work should include a multi-dimensional cancer-specific inventory of the social support constructs to further develop and refine the propositions of social support theory. This represents a considerable knowledge gap and additional research would help to clarify the mechanism effect through which the social support constructs influence coping with prostate cancer, and its relationship with HRQoL. Developing empirical research which is theoretically driven is a prerequisite to the Medical Research Council's framework for complex interventions (Craig et al., 2008), and therefore, developing and refining our theoretical understanding of the social support constructs has never been so important.

The lack of studies conducted in the UK suggests room for improvement and additional research in this field. Furthermore, data only support *aggregate group level effects*. Healthcare research has almost been exclusively restricted to aggregate group level effects, and has neglected the importance of *within-person* experience and change over time. One of the major limitations of the studies included in this review is that of average effects. Thus, applying theoretical constructs to individuals will enrich and expand empirical reach to tailor interventions at the individual level of change (Borckardt et al., 2008). The other major limitation of existing research in this field is retrospective memory recall. Questionnaires are prone to serious errors and biases as a result of autobiographical memory, and this places demands on the participant to accurately recall their experiences (for example, recalling experiences in the past month) (Shiffman et al., 2008, Stone et al., 2005, Stone et al., 2004, Stone et al., 2003a, Stone and Shiffman, 2002). When participants are asked how they felt or how often some event occurred, they rely on heuristic strategies to estimate an answer; they will rely on experiences that are important for them or recent, to provide an answer to the question (Schwartz and Stone, 1998). Consequently, the real-life validity of the data presented from questionnaire based studies is unknown (Jones and Johnston, 2011). In addition, ecological fallacy can also be problematic in the interpretation of group level questionnaire data, whereby inferences about the nature of "individuals" have been incorrectly based on aggregate statistics (Bowling, 2002). To overcome the limitations of aggregate group level effects and

retrospective memory recall, one approach that could be used to advance the field further is case-based time series studies.

Case-based time series studies (Molenaar, 2004) can form the *pre-clinical and theoretical modelling* stages of the Medical Research Council's framework for complex interventions (Craig et al., 2008). The case-based time series methodology is low-cost and has the potential to be very effective in facilitating the early development stages of interventions. Empirically, testing within-person change over time would demonstrate the optimum types of social support that influence HRQoL, whilst assessing changes in coping efforts and self-management behaviours for men living with and beyond prostate cancer and their influence on HRQoL.

Both intervention studies that were reviewed used peer support to form part of the intervention (Carmack Taylor et al., 2007, Weber et al., 2004) but had poor efficacy in improving HRQoL. Interestingly, evidence demonstrated that men with prostate cancer infrequently attend support groups (Krizek et al., 1999) and men have reported little interest in using psycho-social services (Krizek et al., 1999). Moreover, users (men with prostate cancer) of peer support did not have increased HRQoL, more satisfaction, or different coping styles, compared to non-users of peer support (Poole et al., 2001). Whilst the benefits of peer support have been acknowledged elsewhere (Steginga et al., 2004), currently this is an emerging evidence base and it is difficult to reach firm conclusions about the efficacy of this type of support provision. Additional research in this field should include an evaluation of cancer support services to provide a holistic assessment of social support for this patient group.

A restriction to the evidence base presented in this review was the geographical specificity, because the studies were predominately conducted in the USA. Often the samples were mostly white, married, and well educated. Thus the findings are not generalisable to minority groups or worldwide. Despite these limitations, this is an emerging body of evidence that has identified main, moderation and mediation effects of social support on HRQoL prostate cancer survivors. Prostate cancer is now the most common cancer diagnosed in men in the UK, and the number of men set to deal with the aftermath consequences of the disease and its treatments are set to

rise. Therefore, understanding the influence of social support and coping on HRQoL for men affect by prostate cancer is a priority which may contribute towards understanding the needs of these men.

One of the major challenges of this structured review was combining heterogeneous methodologies. Despite this challenge, this review has enabled a broad summary of the evidence which has facilitated a refinement of future research directions in this area.

2.7 Conclusions and research direction

Few prospective longitudinal research designs have been implemented in this field to evaluate changes in social support provision. It seems likely that the types of social support needs will change throughout the cancer trajectory. Additional work is needed to assess how social supportive experiences change over time and this could be achieved through prospective longitudinal designs (to assess aggregate group effects) and case-based time series designs (to assess within-person change over time). Evaluating average group level effects and within-person change over time is an innovative approach which may expand and refine the propositions of social support theory.

A suitable theoretical framework to advance research in this area is the stress buffering model because it links social support and coping to HRQoL. Few studies have tested this theoretical framework within samples of prostate cancer survivors. Importantly, the stress buffering model will enable the effects of social support to be explored with coping and health-related outcomes for this patient group. In addition, future research should test main and mediation effects between the relationship of social support and coping on HRQoL, because developing an understanding of the mechanism effect that links coping and social support to HRQoL will facilitate the development of appropriately targeted interventions that are theoretically driven.

However, social support may not only improve HRQoL, but may also help men in their pursuit to self-manage their condition. Chapter 1 detailed that men living with

prostate cancer (all stages of cancer) can experience reduced HRQoL over time, but little is known about men's self-management behaviours, or the relief achieved from self-management. Chapter 3 will review empirical evidence to identify men's self-management behaviours and establish how they change over time.

3.0 Self-management

3.1 Abstract

Background

Self-management for people affected by cancer is increasingly being recognised as a fundamental component of effective management of cancer care as a long-term condition. Men are keen to engage as active partners in the management of their condition but men have voiced a number of unmet support needs that make effective self-management problematic. Identifying men's self-management behaviours and evaluating how self-management changes over time may provide valuable insights into how men can be better supported to self-manage.

Aim

To review existing research studies that have identified the self-management behaviours for men affected by prostate cancer and that have assessed whether self-management changes over time.

Methods

A structured review of the literature was performed. Databases searched included: DARE, CDSR, Medline, CINAHL, PsycINFO, and ASSIA. Included studies detailed self-management behaviours or assessed changes in self-management over time for men affected by prostate cancer.

Results

111 publications were retrieved from the search and 5 publications were included. Men performed a variety of self-management behaviours for psychological problems and for a number of physical symptoms. Only one study assessed changes in self-management behaviours over time and was limited to men treated by radiotherapy.

Conclusion

Additional research is needed to identify men's self-management behaviours based on different clinical characteristics and different support needs that will generate valuable insights into how men can be better supported to self-manage.

3.2 Introduction

Less than 20% of men diagnosed with prostate cancer will die from this disease, and 93% of men will survive for at least 5 years post-diagnosis (Jemal et al., 2011, Roesch et al., 2005). Therefore, quality of life issues and coping with the chronic physical and psychological problems (as identified from chapter 1 and 2), have never been so important (Guedea et al., 2009) in this patient group. Prostate cancer is managed as a chronic illness requiring long-term surveillance (Oliffe et al., 2009, Hoffman et al., 2006), and in some cases, long-term treatment (Fransson, 2008, Ott and Fulton, 2005).

The Institute of Medicine (McCorkle et al., 2011) identifies six major phases within the cancer care continuum: prevention, early detection, diagnosis, treatment, survivorship and end-of-life care. This continuum illustrates that cancer care extends beyond the treatment phase and requires long-term care provision. Worldwide enablement of self-management for people affected by cancer is increasingly being recognised as a fundamental component of effective management of cancer care as a long-term condition (McCorkle et al., 2011, Department of Health Macmillan Cancer Support & NHS Improvement, 2010, Fenlon and Foster, 2009, Wilson, 2008). With an increase in the number of men living with and beyond prostate cancer, patient engagement in self-management has been advocated as a way of improving physical and psychological well-being (Campbell et al., 2011, McCorkle et al., 2011, The Scottish Government, 2008, Wilson, 2008, Beckmann et al., 2007).

However, the terms *self-care, self-management,* and *self-management support are* often confused, but this is a complex area, although definitions are improving (Jones et al., 2011, Wilson, 2008, Beckmann et al., 2007, Earle, 2007). The following continuum illustrates why such terms often become confused and are often used interchangeably, but they do represent similar notions. Self-care can be viewed as a continuum starting from the individual responsibility that people take in managing daily lifestyle choices, maintaining health and preventing illness (Chambers, 2006). Next along the continuum are behaviours that are associated with the treatment of minor ailments (Porteous et al., 2007), and the final point on the continuum has been

described as healthcare professionals together with patients, helping individuals to cope with long-term conditions. Self-care or self-management have been defined together as a combined term as, “an individual’s efforts to advance optimal health, prevent illness, recognise symptoms as early as possible, and cope with or manage chronic conditions” (Curtin and Mapes, 2001, p386). Thus, defining self-care and self-management together only conflates the confusion in the literature.

Others have defined the terms separately, as self-care refers to an individual’s actions focussing on preventative measures in order to gain or maintain a level of health, whereas self-management is focussed upon disease management generally guided at some point by a clinician and involves the individual making therapeutic adjustments to a treatment regime (Wilson, 2008). Specifically, Wilson’s definition of self-management is suitable within cancer care because this requires long-term planning and on-going relationships between cancer patients and their care providers. Clark (1991) acknowledges that, in general, self-care is interpreted as preventative behaviours that are performed by healthy people at home, whereas self-management is a term used to reduce the impact of disease and to cope with the psychosocial problems in collaboration with healthcare providers.

Self-management can be suggested as a forming of coping (Jones et al., 2011). The assessment of self-management in this patient group may provide an evaluation of coping that is cancer-specific, treatment-specific and symptom-specific (Ahmad et al., 2005). There is a similarity between self-management and coping, in that, they both involve cognitive and/or behavioural attempts to manage the problems associated with cancer and its treatment. Conceptually, the way in which a person copes or appraises the physical and psychological problems in everyday life will influence the type of self-management behaviour performed.

Self-management has been further defined as, “the individual’s ability to manage symptoms, treatment, physical, psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses the ability to monitor one’s condition and to affect cognitive, behavioural, and emotional responses necessary to maintain a satisfactory quality of

life" (Barlow et al., 2002, p 177). Within cancer literature, the term self-management refers to an iterative process whereby individual responses and behaviours are used to cope with the physical and psychological consequences of cancer (McCorkle et al., 2011).

For the purposes of this thesis self-management is conceptualised as an activity that is complex and requires a complex set of skills and activities to manage the physical and psychological consequences of prostate cancer. Such activities might include the the individual to acquire, understand, and evaluate information appropriate to manage their condition, but to also use that information in decision-making. Self-management might also include mobilising resources, that is to say, identifying and activating resources in a timely manner, and the ability to recognise one's own personal limitations or need for support. Finally, self-management might also include collaborating with healthcare professionals and services to make decisions in partnership, and to have the ability to negotiate to get one's needs met successfully.

There has been an emphasis within recent healthcare policy in the UK "Better Cancer Care: An Action Plan" to encourage individuals with cancer to have greater involvement in the management of their condition (The Scottish Government, 2008). Self-management for people affected by cancer can be important for several reasons. Primarily, men living with prostate cancer have unique knowledge and experience of living with cancer and the effects of treatment, therefore, men can contribute to the effective management of these (Hubbard et al., 2007). Men's follow-up care will take place in an outpatient setting, and therefore almost all men will have to manage the after-effects of cancer and treatments, unsupervised by healthcare professionals, in their homes. Consequently, men are being encouraged to participate in their self-management (Hubbard et al., 2007).

Men who have had prostate cancer are keen to engage as active partners in the management of their long-term condition (Mroz et al., 2010, Breau et al., 2003), but they experienced a lack of awareness of available resources (Breau et al., 2003). Prostate cancer survivors have reported unmet informational needs around the following aspects of self-management: management of side-effects, lack of

awareness of appropriate signposting to healthcare professionals, and a lack of dietary and physical exercise advice. Consequently, there is now a growing interest in the development of supported self-management interventions for men who have had prostate cancer (Faithfull et al., 2011, Department of Health Macmillan Cancer Support & NHS Improvement, 2010, Cockle-Hearne and Faithfull, 2010).

A recent self-management intervention study (Faithfull et al., 2011) demonstrated acceptability of self-management interventions for prostate cancer survivors in the UK. The study was quasi-experimental design (Faithfull et al., 2011), aimed at improving the self-management of lower urinary tract symptoms (LUTS) for men (N=15) treated with neoadjuvant hormone therapy and radiotherapy for localised disease. The intervention was based upon cognitive behavioural therapy which aimed to improve: coping strategies, problem solving, informational and emotional support, self-monitoring of urinary symptoms (bladder diary), and pelvic floor exercises. A Prostate Cancer Specialist Nurse delivered the intervention. The primary outcome was International Prostate Symptom Score (IPSS), followed by a number of secondary outcomes: bladder diaries (frequency and volume), HRQoL (EORTC C30 and PR25), and self-efficacy. Overall, the intervention demonstrated a significant improvement in the IPSS scores, improvements in urinary frequency (bladder diaries), and men reported less emotional distress after the intervention. No improvements were identified for HRQoL (physical, social, role or cognitive function, global quality of life) or self-management self-efficacy.

There are several methodological limitations to this study (Faithfull et al., 2011) that are worthy of acknowledgement. The sample size was small (N=15) and underpowered and limits the generalisabilty of the findings to wider populations. An important limitation to the study design was the absence of a control group. Without a control group it is difficult to exclude the possibility that urinary symptoms could have naturally improved over time (Hashine et al., 2005). This study used paper and pen diaries and, therefore, forward and backfilling bias of the bladder diary is possible (Bolger et al., 2003). Faithfull's study did not measure the self-report of self-management behaviours and, therefore, it is possible that the participants could have used additional self-management behaviours that may have influenced

IPSS scores. Despite these limitations, this study has demonstrated acceptability for supported self-management interventions for men affected by prostate cancer.

In summary, identifying the self-management strategies used by prostate cancer survivors is a very important step towards the development of additional supported self-management interventions (Oliffe et al., 2009). The assessment of self-management strategies will facilitate an understanding of the barriers encountered while self-managing, and provide useful insights into how men can be better supported to self-manage (Cockle-Hearne and Faithfull, 2010, Davies and Batehup, 2010).

The purpose of this structured review was to identify the self-management behaviours that men with prostate cancer use and evaluate where or not self-management changes over time. Two research questions were used to guide this structured review:

Research questions:

1) What are the self-management behaviours used by prostate cancer survivors?
2) How does self-management behaviours used by prostate cancer survivors' change over time?

3.3 Methods

A review of qualitative and quantitative research evidence was generated (Centre for Reviews and Dissemination, 2008, Webb and Roe, 2007, Whittemore, 2005). The searches were restricted to the search terms "prostate cancer", "prostate carcinoma", "self-care" and "self-management" (see table 3.1 for search strategy). Databases searched were CINAHL, Medline, PsycInfo, ASSIA, and BNI and key words were mapped to each electronic database using the appropriate MeSH term, or used free search terms. Databases were searched from earliest date available to 2012 using truncation, wildcards and Boolean logic. Additional searches were performed in Index to Theses, Google Scholar, and Google. All of the publications were managed using the software package Endnote X4.

Table 3.1 Search strategy

Search strategy
1. (Subject heading "prostate carcinoma") or (subject heading "prostate cancer")
2. (subject heading "self-care") or (subject heading "self-management")
3. 1 and 2

The titles and abstracts found by the search strategy were reviewed independently by three members of the research team (two of the researcher's Ph.D. supervisors and the researcher) using a pro forma checklist. The pro forma checklist was based on the inclusion criteria (see table 3.2 for inclusion criteria) which facilitated the decision-making process to retrieve full-text articles or not. Publications which met the inclusion criteria were retrieved in full text. Any disagreements were completely resolved through discussion.

Table 3.2 Inclusion criteria

Criteria	Rationale
English text only	Budget constraints and the costs involved for translation
Prostate cancer participants only	This is the primary context of the review; therefore other cancer sites are excluded.
Worldwide literature was included	To capture a broad range of self-management behaviours worldwide.
Does this title/abstract indicate self-management strategies used for prostate cancer survivors?	This is the 1st key focus of the review; to identify the self-report of self-management strategies for prostate cancer survivors.
Does this title/abstract identify how self-management changes over time?	This is the 2nd key focus of the review; to identify whether or not self-management strategies changes over time.
(The publications had to address at minimum, one of the above questions to be considered for inclusion)	

An assessment of the methodological quality of full-text articles was performed. Two quality assessment tools (Shaw et al., 2009) were used because they enabled a wide range of research design to be evaluated. One tool assessed qualitative research designs and the other tool evaluated quantitative research. Key information from the studies was extracted using narrative data extraction sheets. The data extraction was developed based on recommendations from Cochrane Guidelines (2009). The review used a narrative synthesis and tabulation of primary research studies to generate broad findings and conclusions (Whittemore, 2005).

3.4 Results

Of the 111 publications retrieved from the search, 95 were excluded following the application of the inclusion criteria (see figure 3.1). This left 16 publications reviewed in full, and 11 articles (Faithfull et al., 2011, Cockle-Hearne and Faithfull, 2010, Beckmann et al., 2007, Evans et al., 2007, Lev et al., 2007, Ott and Fulton, 2005, Barqawi et al., 2004, Breau et al., 2003, Davison et al., 2002, Landis et al., 2002, Wong et al., 2000) were excluded (see figure 3.1 for reasons for exclusion). This left 5 publications which met the inclusion criteria (2 intervention studies, 1 prospective longitudinal survey, and 2 cross-sectional qualitative studies). An inter-rater reliability analysis using the Kappa statistic demonstrated a high level of agreement kappa= 0.848, p<0.001 (Viera and Garrette, 2005) among the reviewers.

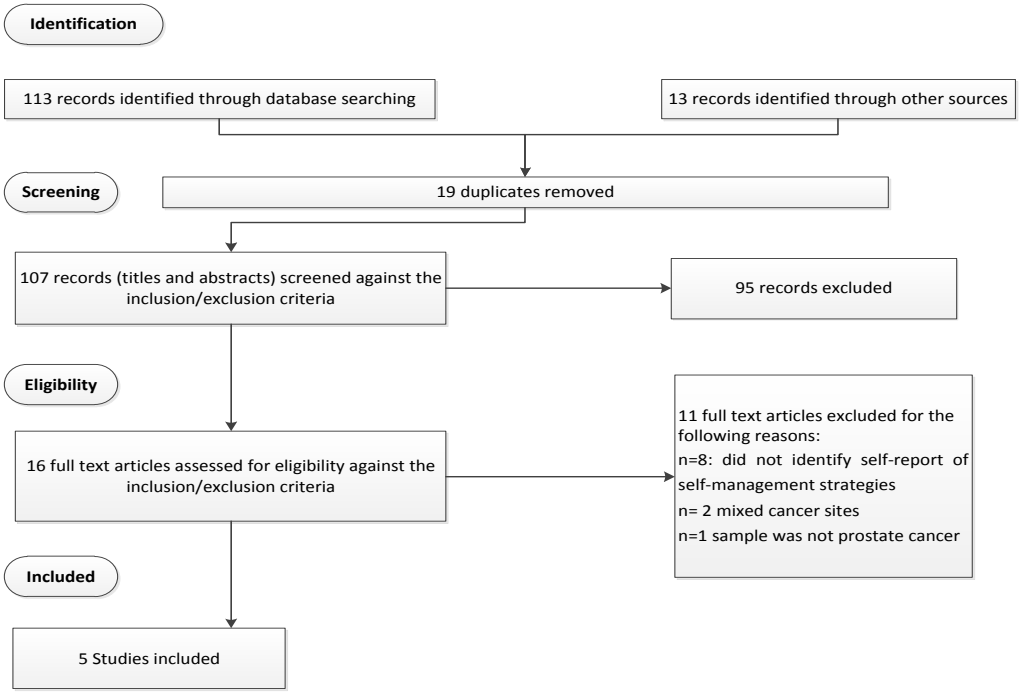


Figure 3.1 PRISMA: Flow of information through different phases of the self-management review (Moher, 2009)

This review included five publications which indicate a lack of research in this field. Two of the studies were conducted in Canada, one in Korea, one in the UK, and one in the USA. The sample sizes were small (N=14 to N=70) with a total sample N=198 across all of the publications. Based on the Department of Health's (2001) typologies

of supporting evidence, the studies ranged from C1 (qualitative research) to B2 (quasi-experimental intervention studies). One qualitative study sampled men undergoing the active surveillance programme for localised prostate cancer (Oliffe et al., 2009), and the other qualitative study sampled men with different treatment modalities (Mroz et al., 2010). The three quantitative studies included samples of men treated with radiotherapy (Wilson et al., 2010) radical prostatectomy (Kim, 2011) and hormone therapy (Hamm et al., 2000). This is an emerging evidence base that includes qualitative data and quantitative data based on samples treated by different modalities. All of the publications (five) reported findings pertinent to understanding the self-management strategies that men used to manage their condition and only 2 studies assessed how self-management strategies changed overtime. Table 3.3 provides an overview of included publications and full data extraction is available in appendix 3.1.

Table 3.3 Studies focused on identifying the self-management strategies to manage prostate cancer and assessed change over time.

Author and Date	Design	Sample	Self-management strategies assessed	Change overtime assessed	Results
(Wilson et al., 2010)	Intervention study: quasi-experimental design. Follow-up 3 weeks into EBRT, final treatment, 3 and 6 months.	70 men before EBRT	Yes	Yes	Most common side effects of EBRT include: skin reactions, dietary problems, emotional reactions and fatigue. Mean of 8 EBRT side-effects were reported (min of 1 and max of 27) reported symptoms. Side-effects onset day 11 (SD 6) into EBRT, lasted approx 8 days. Severity of symptoms 2.8 (mean, SD 0.6), ranged from 1.0 to 4.3 (5 point scale, with 5 being the most severe). Maintaining skin integrity by n=52, used on average 2 out of 5 self-care behaviours, most common "was avoiding exposure of treated area to direct sunlight". Self-management for diet reported by n=57, used 5 of 12 self-care options, most common "eating foods high in protein", Self-care for emotional adjustment was reported by n=53, reported 6 of the 12 self-care options, most common "making a special effort to maintain a positive attitude and consciously trying to think more positively". 60% of participants reported taking more rest periods as self-care strategies to alleviate fatigue. Self-care actions significantly increased overtime from BL to 6M (12.2, SD 7.0 vs. 13.9 SD 6.1; t=1.94, P=.05). Intervention had no effect.
(Kim, 2011)	Intervention study: quasi-experimental design. Follow-up 2 months post-surgery	69 men before RP	Yes	No	Self-management activity score of the experimental group 30.39 points, control group 29.64 points (possible score range from 9 – 36). No description is given to interpretation of the scores or a description of the actual self-care strategies.
(Hamm et al., 2000)	Prospective longitudinal design: Follow-up assessed over 5 visits (1, 2, 3, 4, 12 months).	20 men (all at different trajectories) self-injection of HT	Yes	Yes	Men self-injection demonstrated good compliance for a subsample. 55% of the men injected 5 times over 12 months, demonstrating 100% compliance to treatment regime. No additional self-care was reported in this publication. Reasons for non-compliance: too intricate, partners concerns, interference of work commitments, difficulties with travel.
(Oliffe et al., 2009)	Qualitative, cross-sectional design.	25 men <2 years on the active surveillance programme	Yes	No	Over-arching theme of "Uncertainly" emerged, "…when you are told you have cancer, I mean it sticks with you, cancer is cancer, I don't care if I have low grade or not and nobody could tell me that there's no cancer growth there, there's no, um, spreading of cancer, they can't tell men that, which really frustrates me". Self-management of uncertainty was managed by 2 strategies "living a normal life" and "doing something extra". The theme of living a normal life reflected men's positions to view their cancer as benign (n=14) "get out of jail free card". Self-management related to "doing something extra", which focussed on dietary modifications " to go on AS has more to do with diet change…it goes hand in hand". Men reported eating less, taking supplements including saw palmetto, green tea, tomatoes, pomegranate juice.
(Mroz et al.,	Qualitative, cross-	14 men < 5	Yes	No	

2010)	sectional design	years since diagnosis, mixed treatments			Diet change self-management included the following themes: “pre-cancer diet perceptions’”, “diet and health understandings”, “perceptions of prostate cancer”, and their need to “do something” for self-care. Cancer was viewed as a chronic condition required on-going management and men expressed a need to “do something” about it. “…PSA shows up well then I’ll probably get a little excited again and then go on, figure out what to do. But then I’ll probably start learning a lot more about fine-tuning my diet or whatever…” Overall perceptions influenced the dietary eating habits and included a number of sub-themes: 1) already had a healthy diet; “I’ve always eaten healthily and I will continue to eat healthily but I’m not expecting it to cure cancer”, 2) diet does not affect prostate cancer recovery “It’s not a disease that once you have got it diet’s going to do much for you”. 3) Won the war, “you might as well go out and do what you want”, 4) diet and health understandings, “I want to live a longer life and I want to live it well... diet is one of the few things I can do”.

3.4.1 What are the self-management strategies used by prostate cancer survivors?

This section begins with an overview of the approaches used to measure the self-management behaviours for men affected by prostate cancer. Three quantitative studies (Kim, 2011, Wilson et al., 2010, Hamm et al., 2000) assessed men's self-management behaviours by different approaches and an overview of the measurements used are summarised in table 3.4.

Table 3.4 Overview of measurement approaches for self-management behaviours for men affected by prostate cancer

Author	Sample characteristic	Measurement	Items	Validity and reliability
(Wilson et al., 2010)	N=70 EBRT	Self-care log (SCL) (Dodd, 1982)	2 components: 1) list of 56 possible side effects 2) self-management behaviours, perceived effectiveness, and severity of symptoms (Developed for patients receiving chemotherapy).	**Content validity:** expert critique (10 oncologist, 4 patients, 4 specialist nurses) **Convergent validity**: using the symptom scale of the SCL, the SCL correlated with the Omega Screening Questionnaire (r=.39, p<.001) and physical problems documented in the medical notes, (r=.47, p<.001).
(Kim, 2011)	N=69 RP	Self-care activity questionnaire	10 items: usage of incontinence pads, frequency of pelvic floor exercises, and self-management strategies for the following: haematuria, constipation, activities restrictions, smoking cessation, hospital appointments, and utilising family support systems	**Reliability:** Dodd (1982) demonstrated good reproducibility (85%) of the SCL when in interview format. Cronbach's alpha not reported. **Content validity:** Expert critique (Urologist Professors' and specialist nurse. But patients' comments were not included.
(Hamm et al., 2000)	N=20 men self-injecting HT*	No questionnaire measurement	Verbal reports from participants at clinical visit with regards to compliance to self-injected HT*	**Reliability:** Internal consistent reliability; Cronbach's alpha 0.64 Blood assessment of PSA and testosterone as a measurement of adherence to self-injected HT.

*HT (Hormone therapy)

Hamm et al., (2000) identified that men can self-inject hormone therapy as a self-management behaviour for the treatment of prostate cancer. Hamm's study did not use an instrument to assess self-management strategies, but verification of medication adherence (the self-management behaviour) was assessed during verbal consultation at clinics and assessed using blood tests (PSA and testosterone levels). Hamm's study did not detail additional self-management strategies that men may have performed, for example, the self-management strategies used to relieve symptoms associated with the hormone therapy.

Kim (2011) assessed the self-management behaviours for men who had undergone radical prostatectomy. Kim developed the Self Care Activity Questionnaire for the purpose of her research. This instrument had 10 items and assessed the following: usage of incontinence pads, frequency of pelvic floor exercises, and self-management strategies used for haematuria, constipation, activity restrictions, smoking cessation, hospital appointments, and utilising family support systems. One limitation to Kim's instrument was the non-assessment of self-management behaviours used to relieve sexual dysfunction because impotence can be problematic for men after surgery (Darst, 2007, Kendirci et al., 2006, Bokhour et al., 2001). Internal consistency (Cronbach's alpha .64) of Kim's instrument was unsatisfactory based on recommendations from Rattray and Jones (2005). Face validity was assessed through comment from healthcare professionals only, thus no comment was sought from men treated by surgery. This lack raises a concern about the content validity because no comment from men affected by this condition was sought during the development of the Self Care Activity Questionnaire. This challenges the content representativeness and relevance in accurately capturing men's experiences of self-management (Lynn, 1986).

Wilson (2010) used Dodd's (Dodd, 1997, Dodd, 1982) Self-Care Log (SCL) for the evaluation of self-management behaviours for men treated with neoadjuvant hormone therapy and radiotherapy. One of the major strengths of the SCL is the identification of a) symptoms, b) self-management behaviours, and c) perceived relief of self-management actions. The SCL has been used in the measurement of self-management actions of cancer patients undergoing chemotherapy and radiotherapy (Kidd et al., 2008, Wong et al., 2006, Borthwick et al., 2003, Richardson and Ream, 1997, Nail et al., 1991, Dodd, 1982). Content validity was established by expert critique from: 10 oncologist, 4 patients, 4 specialist nurses, and is in keeping with recommendations from Lynn (Lynn, 1986). Convergent validity was demonstrated by correlating the symptom scale of the SCL with the Omega Screening Questionnaire ($r=.39$, $p<.001$) and also correlating the symptoms scale of the SCL with the physical problems documented in the medical notes ($r=.47$, $p<.001$). Internal consistency of the SCL has not been reported, however Dodd reported a good level of reproducibility (85%) when comparing the written SCL with the SCL in interview format. Based on the reviewed studies that quantitatively measured self-management actions for prostate cancer survivors, the SCL would be the strongest

instrument for additional research in this field because of a number of important considerations: 1) this instrument has been widely applied to previous self-management research for people affected by cancer, 2) reliability and validity of this instrument has been demonstrated, and 3) the SCL evaluates the identification of a) symptoms, b) self-management behaviours, and c) perceived relief from self-management actions.

Self-management behaviours

This section will present the findings to address the first research question: what are the self-management behaviours used by prostate cancer survivors? A number of self-management strategies were reported by men (N=70) treated with radiotherapy to relieve a range of physical and psychological factors: skin reactions, dietary problems, emotional reactions and fatigue (Wilson et al., 2010). Maintaining skin integrity was reported by 52 men who used on average 2 out of 5 self-management behaviours, the most common reported self-management behaviour was, “avoiding exposure of treated area to direct sunlight”. Dietary modification was reported by 57 men and used on average 5 of the 12 self-management options and the most common action reported was “eating foods high in protein”. Self-reports of self-management for emotional adjustment was reported by 53 men and used 6 of the 12 self-management options and the most frequent self-management action, “making a special effort to maintain a positive attitude and consciously trying to think more positively”. Over half (60%) of the sample reported taking more rest periods as self-management strategies to alleviate fatigue. This study used the SCL (Dodd, 1982) and has provided a useful insight into the behaviours of men treated with radiotherapy.

Kim (2011) developed an instrument to measure self-management behaviours in a sample (N=69) treated by radical prostatectomy. The findings from Kim’s study are very difficult for the reader to interpret. The data presented from Kim’s study identified a value of 30.39 to represent self-management activity, but it is unclear what this represents: the mean, median or total score and the actual self-management actions were not reported. Kim’s intervention (see appendix 3.1 for intervention overview) promoted self-management in the following areas: symptoms, catheter management, urinary incontinence, post-surgery exercise, diet

and defecation, pelvic floor exercises, which provides anecdotal evidence of proxy self-management activities for men treated by surgery.

The last quantitative paper in this review (Hamm et al., 2000) identified men who self-injected hormone therapy for the treatment of their cancer, but this publication did not identify other self-management behaviours. For example, the self-management behaviours used to relieve the side-effects of hormone therapy: nausea, decrease in appetite, constipation or diarrhoea, gynecomastia, sleeping difficulties, sweats and flushes, depression, impotence and osteoporosis (Cancer Research UK, 2011, Couper et al., 2009) were not assessed.

An overview of the self-management behaviours across the reviewed publications are presented in table 3.5. The findings from the three quantitative studies have identified that this is an emerging evidence base, but little is known regarding the self-management behaviours or the effectiveness of mens' actions in alleviating problems/symptoms. There are large gaps in the evidence whereby it is unclear how self-management differs across the stages of cancer (localised, locally advanced and metastatic). This area would be worthy of further research to assess the problems/symptoms experienced and the self-management behaviours used to identify opportunities towards developing better supportive care.

Table 3.5 Overview of the self-management strategies identified from the reviewed quantitative publications

Author	Stage and treatments	Problems/symptoms	Self-management action
Wilson et al., 2010	Cancer stage no reported N=70 treated with radiotherapy	Skin reactions Dietary problems Emotional problems Fatigue	*The most common self-management action was only reported in the publication:* Avoiding exposure of treated area to direct sunlight Eating food high in protein Reducing risk of infection by avoiding crowds or people with colds and by washing hands more often Making a special effort to maintain a positive attitude and consciously trying to think more positively Taking rest periods and getting help with chores
Hamm et al., 2000	Locally advanced/metastatic cancer N=20 men treated with hormone therapy	Not assessed	Self-injection of hormone therapy (five injections over the course of twelve months)
Kim, 2011	Localised and locally advance cancer N=69 men treat with radical	No assessed	Self-management activity was reported as a value of 30.39, it is unclear whether this value represents the mean, median, mode, and total score. The author does not

	prostatectomy		identify self-management behaviours. Proxy accounts of self-management may include: symptoms, catheter management, urinary incontinence, post-surgery exercise, diet and defecation and pelvic floor exercises.

Two studies included in this review provided qualitative insights into men's experiences of self-management. A cross-sectional study (Oliffe et al., 2009) explored men's (N=25) self-management behaviours who underwent active surveillance. Findings identified an overarching theme of "uncertainty" which was associated with men's experience of active surveillance. Uncertainty has been described as a psychological stressor that occurs as a consequence of being unable to determine the meaning of an illness-related event, and the inability to predict illness outcomes accurately (Mishel, 1990, Mishel, 1988). Men spoke about their worries of their cancer spreading and the following quote represents this,

"… when you are told you have cancer, I mean it sticks with you, cancer is cancer, I don't care if I have low grade or not and nobody could tell me that there's no cancer growth there, there's no, um, spreading of cancer, they can't tell me that, which really frustrates me."

(Oliffe et al., 2009, p.435).

This quotation highlights that this man experienced uncertainty of cancer progression, and illuminates the psychological impact of the active surveillance programme. This man understood that his cancer was not aggressive, but this did not appear to lessen the psychological impact of a prostate cancer diagnosis. This quote may represent that this man was concerned about the monitoring techniques (digital examination, PSA, prostate biopsies) used and their sensitivity to detect subtle changes in his cancer progression. Other men spoke about the uncertainty of coping with treatment-induced side effects of erectile dysfunction,

"You know, a man's identity I guess is pretty much what women say, it's all about your penis [laughs] you know … that's the way we're programmed so I just want to do everything to save my penis."

(Oliffe et al., 2009, p.436).

This quote may represent this man's masculinity and the strategy of being on the active surveillance programme as a means to avoiding the devastating consequences related to curative treatments: impotence, urinary incontinence and bowel problems. The third area of uncertainty was related to the result of the digital examination, PSA and prostate biopsies,

"It's a little scary … every time I come up to my six months visit … I have a little bit of anxiety and then we do the digital and everything is fine … and the PSA is fine … phew got another six months."

(Oliffe et al., 2009, p.436).

Oliffe identified that men appraised uncertainty as a psychological stressor and used two self-management strategies: "living a normal life" and "doing something extra" to cope with the psychological impact of uncertainty (stressor). The theme of "living a normal life" reflected men's (n=14) perception of their cancer as benign (Oliffe et al, 2009),

"The way Dr [name] explained it ... the anxiety side was completely gone. If somebody turns around and says that you know five years down the road or ten years down the road that nothing immediate ... no pills or anything like that ... just leave it alone and keep it under active surveillance and that takes all the anxiety and everything ... from that point it's a less consideration than possibly having a toothache."

(Oliffe et al., 2009, p.436).

The second emergent theme of "doing something extra" was focussed on dietary modifications,

"… to go on active surveillance has more to do with diet change … it goes hand in hand."

(Oliffe et al., 2009, p.438).

"… taking anything whether it's proven or not ... if there is a hint that it will slow the growth or reduce cancer in general."

(Oliffe et al., 2009, p.438).

Men also spoke about eating less, and taking supplements which included: saw palmetto, green tea, tomatoes, and pomegranate juice.

The findings from Oliffe's study can be linked to Lazarus and Folkman's (1984) theory of stress and coping. According to the transactional model, one's interpretation/appraisal of a stressful event (uncertainty of active surveillance) is believed to determine how one would cope with this experience. The findings presented here identified different coping strategies that emerged from the data, "living a normal life" and "doing something extra". Men who appraised the stressor of uncertainty as benign are likely to have adjusted to being on active surveillance by "living a normal life" because men identified their anxiety was completely gone (Oliffe et al., 2009). For others, uncertainty was appraised as a stressor, and men used dietary modifications as a self-management behaviour to reduce the worry of cancer progression and thus, aimed to avoid the sequelae of physical and psychological problems related to curative treatments.

This study has provided useful insights into the self-management experiences for men undergoing active surveillance that can be linked to the stress and coping theory. The limitation to this study is the cross-sectional qualitative design and therefore, it is not possible to capture changes in self-management behaviours over time. Survey data have identified that men undergoing active surveillance can experience urinary, bowel, and sexual dysfunction (Thong et al., 2009), yet Oliffe did not report any self-management behaviours related to these problems. It may be however, that coping with the uncertainty was more salient for the men in Oliffe's study, and this would seem a likely explanation because the experience of uncertainly has been reported elsewhere (Hegarty et al., 2008).

A further study (Mroz et al., 2010) explored men's perceptions of their diet change in a mixed treatment sample at different cancer trajectories. Prostate cancer survivors' self-management of diet change was complex and involved a number of factors, and these included: pre-cancer diet perceptions, diet and health understandings, perceptions of prostate cancer, and "their need to do something for self-management". Men expressed a need to modify their diet to increase overall health and survival. Some of the dietary modifications included: taking lycopene, selenium, soy products, tomatoes, broccoli, fruit and vegetables and reducing red

meat. The following quotes represent the need to modify dietary intake to increase overall health and survival,

> "Now I have finished my prostate cancer treatment, it's like, Okay, now we're going to get smart about what we're doing about diet and be sure that we don't adversely influence the healing by what we are eating."
>
> (Mroz et al., 2010, p.402).

> "I want to live a longer life and I want to live it well in the absence of disease and diet is one of the few things I can do that would help."
>
> (Mroz et al., 2010, p.402).

Mroz's study could also be linked to the stress and coping theory (Lazarus and Folkman, 1984) because positioning diet change can be a positive coping behaviour. Men conceptualised their prostate cancer as a chronic condition that was associated with reduced health and overall survival (stressor). Following men's individual appraisals of the stressful encounter (health problems) men may have used dietary modifications to cope with the adverse effects of this stressor. Mroz's study identified diet change as self-management behaviour for men treated for prostate cancer. One of the limitations to Mroz's study is the homogeneity of demographic variables within the sample. The sample was mostly retired, college educated and affluent, and therefore, limits the transferability of the results to people who are of different demographic groups. Additional self-management strategies were not reported in this paper, such as self-management for urinary, bowel and sexual dysfunction problems. One possible explanation for this deficit is that the researcher represented himself as a nutritional student to the participants. Bias is possible because the men may have discussed their experiences differently with someone who did not have a nutritional background. Due to the limitation of the cross-sectional qualitative design, changes in self-management experiences over time were not assessed.

3.4.2 How do self-management strategies used by prostate cancer survivors' change over time?

Of the reviewed studies, only two studies (Wilson et al., 2010, Hamm et al., 2000) have provided evidence to advance understanding of change over time. Hamm and colleagues demonstrated the potential for men to treat their prostate cancer through self-injection of hormone therapy. Hamm identified that men (n=11) self-injected hormone therapy on five occasions over the course of 1 year, whereas, Wilson's study identified a significant increase over time in self-management activities from before radiotherapy to 6 months follow-up (12.2, SD 7.0 vs. 13.9 SD 6.1; t=1.94, P=.05). The main symptoms experienced included skin reactions, dietary problems, emotional problems, and fatigue, but Wilson did not identify how individual self-management behaviours changed in relation to the symptoms experienced over time. The findings presented here suggest that self-management behaviours may increase over time, but there are gaps in current knowledge that will be addressed in the discussion.

3.5 Discussion

There were a number of methodological limitations that featured across the reviewed publications. Two quantitative studies (Wilson et al., 2010, Hamm et al., 2000) did not conduct a power calculation to define their sample sizes, nor did they provide a rationale for not performing this analysis. It is possible that Wilson's and Hamm's studies lacked statistical power to make statistical judgments about self-management that were accurate and reliable. Four (Kim, 2011, Wilson et al., 2010, Mroz et al., 2010, Hamm et al., 2000) studies did not identify the total number of participants approached and therefore, selection bias is possible. Consequently, the study populations may not have adequately reflected the spectrum of characteristics of men affected with prostate cancer (Sica, 2006) and this lack limits the generalisabilty of their findings.

Attrition was reported in one study (Hamm et al., 2000) of the three prospective longitudinal designs. Hamm's study aimed to test the feasibility and acceptability of men self-injecting hormone therapy. The attrition rate in Hamm's study was very high (45%) and men withdrew their consent for a number of reasons, including the following: injection technique was too intricate, concerns from partners, and

travelling distances. Self-injecting hormone therapy was only acceptable to 55% (n=11) of the original sample. Hamm and colleagues did not statistically test for unique characteristics between the men lost from the study and those men who remained in the study. Consequently, the remaining sample (n=11) may not be representative of the original sample and limits the generalisabilty of their findings.
The sample sizes for the two qualitative research studies were N=14 (Mroz et al., 2010) and N=25 (Oliffe et al., 2009) and both studies used convenience sampling. The researchers did not sample men who were representative of the entire population, and thus limits the transferability of the results. However, the qualitative studies in this review have provided a useful insight into men's experience of self-management in relation to prostate cancer. The findings from both studies (Mroz et al., 2010, Oliffe et al., 2009) can be theoretically linked to the Lazarus and Folkman's (1984) stress and coping theory. Coping with everyday problems (stressors) has been associated with the type of self-management behaviours used by people affected by cancer (Foster and Fenlon, 2011) and has been identified for prostate cancer survivors (Oliffe et al., 2009). Conceptually, the outcome of self-management is to minimise the effect of cancer on physical health and functioning, and to cope with the psychological sequelae (Jones et al., 2011).

The studies reviewed identified self-management behaviours for men undergoing active surveillance (dietary modifications), mixed treatment group (dietary modifications), hormone therapy (self-injecting) and radiotherapy (avoiding exposure of treated area to direct sunlight, dietary modifications, reducing risk of infection by good hygiene, maintaining a positive attitude, taking rest periods and getting help with chores). Self-management was performed for psychological and physical problems, namely: psychological problems: uncertainty and emotional problems, and physical symptoms: skin reactions, fatigue and dietary problems. However, men can experience a number of additional problems/toxicities associated with prostate cancer that the current state of the evidence does not address. Such problems include: urinary (urgency, infrequency, incontinence) (Zelefsky et al., 2008), bowel (rectal bleeding, urgency in defecation, diarrhoea, and faecal leakage) (Al-Abany et al., 2002) and sexual dysfunction (impotence, loss of libido) (Gomella, 2007).

The evidence does not sufficiently detail how self-management behaviours change over time in relation to the toxicities experienced as a result of prostate cancer and

treatment. Only one study (Wilson et al., 2010) assessed change over time using a standardised instrument (SCL, Dodd, 1984). Wilson and colleagues detailed that self-management increased over time, from beyond the acute treatment phase to 6 months after radiotherapy. Caution is given to the interpretation of these findings because co-morbidity was not measured in this sample. Increases in self-management behaviours could be a consequence of an increase in general symptoms and not as a direct result of prostate cancer. To overcome the potential for co-morbidity bias in future research, co-morbidity should be measured and controlled for in the research design (Kerr et al., 2007). Wilson did not detail which self-management behaviours increased over time. Therefore, additional research should detail which specific areas of self-management increase over time to tailor support as appropriate.

A further limitation to Wilson's study was the use of paper and pen diaries to assess change over time. Participants can forward and backfill paper diaries, and this method consequently reduces the accuracy and reliability of data collected (Stone et al., 2003b). One possible method to overcome the limitation of paper and pen diaries is electronic diaries with compliance-enhancing features. Electronic diaries with compliance-enhancing features can remove the bias of forward and backfilling effectively, whilst accurately evaluating changes in the variables of interest over time (Blondin et al., 2010, Piasecki et al., 2007, Gaertner et al., 2004). Innovative technology such as electronic diaries would have the potential to effectively capture self-management over time for prostate cancer survivors. Acceptability of electronic means of data collection has been demonstrated in participants with long-term conditions (Kerkenbush and Lasome, 2003, Peters et al., 2000) and cancer groups (Badr et al., 2010, McCann et al., 2009, Kearney et al., 2009, Forbat et al., 2009). Electronic diaries would have the potential to overcome some of the methodological limitations to accurately evaluate self-management behaviours over time.

This review has identified that research in the UK is very limited, although there is an emerging interest in self-management interventions for prostate cancer survivors (Faithfull et al., 2011, Cockle-Hearne and Faithfull, 2010). The findings from this review identified that little is known regarding the actual self-management behaviours used by men across all stages of disease/treatment modalities and this has been reported elsewhere (Flynn and Groot, 2009). Additional research that aims

to assess the dynamic nature of self-management behaviours across different clinical characteristics will provide useful insights in to how men can be better supported to self-manage their condition. Work in this area is paramount because men have voiced a number of physical and psychological unmet needs related to their self-management.

Men with prostate cancer have reported that they have unmet support needs (Boberg et al., 2003, Lintz et al., 2003) which resulted in them frequently having to cope with the physical and psychological sequelae of their treatment on their own. The identified areas of unmet needs include psychological distress, sexuality-related issues and the management of enduring lower urinary tract symptoms (Ream et al., 2008). Men with prostate cancer have voiced a need for informational support, particularly regarding the side-effects of the disease, associated treatments and on-going issues related to recurrence (Carter et al., 2011, Boberg et al., 2003). Prostate cancer survivors are keen to engage as active partners in the management of their condition (Mroz et al., 2010), but men often feel inadequately supported to do so (Department of Health Macmillan Cancer Support & NHS Improvement, 2010, Breau et al., 2003).

Social support has been found to improve participation in self-management of long-term conditions (Schiøtz et al., 2012, Gallant, 2003, Barrera et al., 2002, Gleeson-Kreig et al., 2002). Therefore, social support (discussed in chapter 2, section 2.6) has the potential to influence the appraisal of everyday problems and subsequently improve coping efforts, but social support may also improve participation in self-management for men affected by prostate cancer. Given the distinct number of unmet support needs for men affected by this disease, social support has the potential to influence coping and self-management for men and improve subsequent HRQoL. Currently, the role of social support and self-management has not been evaluated for men affected by prostate cancer, but this area would be worthy of additional research. Knowledge in this area may identify directions for self-management support.

Limitations

It is important to acknowledge the potential limitation of the search strategy used in this review. The search terms used had a high level of specificity, and therefore, the

search terms may not have been sensitive in identifying all of the relevant literatures. An important omission in this review was that “coping and adjustment” were not included in the search terms, and as a result, it is possible that not all relevant literatures were included and reviewed. Furthermore, a potential limitation of the review methodology was that the inclusion criteria consisted of the levels of evidence, and therefore, potentially relevant studies may have been excluded because of research design, for example, Cockle-Hearne and Faithfull, (2010).

3.6 Overall summary of the chapter

This review has identified that very little research has assessed self-management behaviours for prostate cancer survivors. There were five papers included in this review and this underscores that this field is under-developed. Additional research is urgently needed to develop this evidence base through the identification of the self-management behaviours for men affected by prostate cancer with different clinical characteristics and levels of social support. Knowledge in this area is important because of the number of unmet support needs of these men, and the recent political drive for individuals to self-manage (The Scottish Government, 2008). The current state of the evidence has a number of methodological limitations that limits the transferability and generalisation of the findings to the wider prostate cancer population.

This is an emerging evidence base that has identified men can experience psychological and physical problems for which men perform self-management. Men can experience a number of additional problems/symptoms for which they perform self-management but currently no data exist which details such self-management behaviours. Only one study assessed changes in self-management over time, but was limited to men treated by radiotherapy. The current state of the evidence does not detail how men’s self-management behaviours change in relation to severity of cancer stage or individual treatment modality. Identifying self-management behaviours for men with different clinical characteristics and different support needs may generate valuable insights into how men can be better supported to self-manage.

In summary, this structured review has identified that little is known about the self-management behaviours or details how they change over time. Therefore, this Ph.D.

study will identify the actual self-management behaviours for men with different clinical characteristics/support needs and evaluate how self-management changes over time.

4.0 Methodology

4.1 Abstract

Background

Chapters 1, 2, and 3 identified that little is known about the influence of social support and coping on HRQoL for men affected by prostate cancer. Furthermore, very little evidence details the self-management behaviours of men affected by prostate cancer, or how self-management changes over time. The assessment of self-management behaviours can be considered as a specific type of coping that is cancer-specific, treatment-specific and symptom-specific. Identifying the self-management behaviours for men with different clinical characteristics and different support needs may generate valuable insights into how men can be better supported to self-manage.

Aims

The purpose of this Ph.D. study was to test the mechanism effect of coping and social support on HRQoL between individuals and within individuals over time. This Ph.D. study also aimed to identify the self-management behaviours of men affected by prostate cancer over time.

Methods

A quantitative approach consisted of a prospective longitudinal survey and 12 ecological momentary assessment (EMA) adapted/ N-of-1 studies which were appropriate to address the overall study aim. The methodological considerations of the prospective longitudinal survey and the EMA adapted/ N-of-1 case study will be critically considered in the introduction of this methodology chapter. Participants were asked to complete a battery of questionnaires at baseline and 6 months follow-up (HADS, EORTC C30 + PR25, PSS, MAC Scale, BSSS, self-care self-efficacy, prostate specific self-care diary). A sub-sample (n=12) completed a daily electronic diary for a total duration of one month. The duration, timing and design of the EMA adapted/N-of-1 were guided by the literature and expert comment from the Ph.D. steering group.

Relevance

This methodology aimed to test the theoretical model between people and within individuals over time to advance understanding, but uniquely positioned the individual man at the centre of this research. This design enabled refinement of the propositions of social support theory. The design and methods chosen in this Ph.D.

study were important for providing insights into, and quantifiable data on, men's social support and self-management behaviours over the course of their cancer journey.

4.2 Introduction

This chapter describes the methods used in this Ph.D.. Chapter 1 identified that prostate cancer survivors' HRQoL improves by 12 months after diagnosis, but men can experience enduring urinary, bowel and sexual dysfunction for many years following treatment. Assessing changes earlier in the cancer trajectory may provide useful insights into how HRQoL can be improved and restored sooner in the cancer journey. For example, understanding men's experience of the potential barriers to self-manage earlier in the cancer journey may provide useful insights for the development of appropriately targeted interventions. The findings from the HRQoL structured review (chapter 1) identified a number of demographic variables (age, ethnicity, marital status, education), clinical variables (co-morbidity, Gleason, TNM classification, treatments, and PSA) and psycho-social variables (anxiety and depression, coping, self-efficacy, perceived stress and social support) that have been found to predict HRQoL for men affected by prostate cancer.

Little psycho-social research (Zhou et al., 2010a, Zhou et al., 2010b, Kershaw et al., 2008, Roberts et al., 2006, Visser et al., 2003, Van Andel et al., 2003) has been conducted to identify the relationship between coping and social support on HRQoL during the pre-treatment to six month post treatment trajectory (Bloch et al., 2007). The importance of social support as a resource for people affect by cancer is not a new concept, but specifically, prostate cancer survivors have reported a lack of support for their unmet physical and psychological problems (Ream et al., 2008, Boberg et al., 2003, Lintz et al., 2003). HRQoL is likely to be affected by the psychological and social factors that unfold over time as men manage, learn from, and adjust to the changes caused by prostate cancer and its associated treatments (Roberts et al., 2006). The findings presented in chapter 3 identified that little evidence exists that details the self-management behaviours which can be considered as a form of coping that is cancer-specific, treatment-specific and symptom-specific (Ahmad et al., 2005). Understanding the mechanism effect of how coping and social support operate on HRQoL over time can help to identify men who are at high risk and suggest directions for intervention (Roesch et al., 2005).

Few prospective longitudinal research designs have been implemented to evaluate changes in social support provision. It seems likely that the types of social support needs will change throughout the cancer trajectory. Additional work is needed to assess how social supportive experiences change over time and this could be achieved through prospective longitudinal designs (to assess aggregate group effects) and case-based time series designs (to assess within-person change over time). Evaluating average group level effects and within-person change over time is an innovative approach which may expand and refine the propositions of social support theory.

A suitable theoretical framework to advance research in this area is the stress buffering model (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984) because it links coping and social support to HRQoL. Few studies have tested this theoretical framework within samples of men living with and beyond prostate cancer. Importantly, the stress buffering model will enable the effects of social support to be explored with coping and health-related outcomes for this patient group. Future research should test main and mediation effects between the relationship of social support and coping on HRQoL, because developing an understanding of the mechanism effect that links coping and social support to HRQoL will facilitate the development of appropriately targeted interventions that are theoretically driven.

The purpose of this Ph.D. study was to test mechanism effect of coping and social support on HRQoL between individuals and within individuals, capturing change over time. In addition, this research aimed to assess the self-management behaviours of men affected by prostate cancer. A quantitative approach combining prospective longitudinal surveys and 12 ecological momentary assessment (EMA) adapted/ N-of-1 studies was considered appropriate to address the aim of the Ph.D. study. A prospective longitudinal survey aimed to assess change over time and predictors of HRQoL outcomes (Galvao et al., 2010, Parker et al., 2009, Carmack Taylor et al., 2006, Holmbeck, 2002). The prospective longitudinal survey was used to test the social support theoretical model (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984) across a group level effect (between individuals). Prospective longitudinal surveys have a number of problems associated with them, for example, retrospective memory recall and ecological fallacy (Bolger et al., 2003,

Bowling, 2002, Holmbeck, 2002). To overcome the problems inherent in the prospective survey design a series of EMA adapted/N-of-1 studies was conducted (Molenaar, 2004). The problems associated with the prospective longitudinal survey and the EMA adapted/N-of-1 will be considered in greater detail.

Prospective longitudinal survey design

The prospective longitudinal survey design in healthcare research has many advantages. A prospective longitudinal design enables change over time to be assessed for HRQoL in prostate cancer survivors (Ash et al., 2007) and prediction of study outcomes, that is to say HRQoL (Zhou et al., 2010a), and, therefore, is well suited to address the aim of this Ph.D.. This design does have some limitations that are acknowledged. Although the prospective longitudinal survey design was prospective, it included retrospective questioning about experiences that occurred in the past. Memory recall bias is possible due to collecting retrospective self-reports about real-world behaviour through questionnaires. Questionnaires are prone to errors and biases as a result of autobiographical memory, because it is difficult for participants to accurately recall their experiences (for example, recalling experiences in the past month) (Shiffman et al., 2008, Stone et al., 2005, Stone et al., 2004, Stone et al., 2003b, Stone et al., 2003c, Stone and Shiffman, 2002). When participants are asked how they felt or how often some event occurred they rely on heuristic strategies to estimate an answer and often participants rely on experiences that are recent or important for them to provide an answer (Schwartz and Stone, 1998). Therefore, the “real-life” validity of the data presented from questionnaire based studies is unknown (Jones and Johnston, 2011). Ecological inference fallacy can also be problematic in the interpretation of group level questionnaire data, whereby inferences about the nature of “individuals” are incorrectly based on aggregate statistics (Bowling, 2002). Clinically, this is important because any theory underpinning an intervention should be supported empirically at the level to which it is applied; to the “individual patient”.

Ecological Momentary Assessment (EMA) adapted/N-of-1

To overcome the limitations of the prospective longitudinal survey, an ecological momentary assessment (Stone and Shiffman, 1994) has been shown to capture experiences as they occur in real time and minimises recall for the participant. The EMA design allows the capture of data of interest repeatedly in real time in the participants' natural environment (Shiffman et al., 2008). Researchers are now using the EMA approach to assess health-related symptoms and behaviours in patients with a variety of conditions, including pain (Aaron et al., 2005, Stone et al., 2003c), asthma (Hyland et al., 1993), heart disease (Kinne et al., 2001), arthritis (Lefebvre et al., 1999) and cancer (Kearney et al., 2009, Curran et al., 2004). The EMA approach has been shown to capture participants' experiences over time which may vary from days, weeks or months (Shiffman et al., 2008). There are different methods of conducting EMAs but the method of choice is through the application of an electronic diary (Schwartz and Stone, 1998). The advantages of electronic versus paper dairies have been reviewed elsewhere (Piasecki et al., 2007, Stone et al., 2003b) and such benefits include: reduced data fabrication, increased participant compliance and better accuracy and efficiency in data collection. The cardinal advantage to using this approach is that the electronic diary data are collected in real time, which is date and time stamped (at the time of data entry), and therefore minimises the risk of introducing retrospective memory recall (Stone et al., 2005, Stone et al., 2004). EMA data can provide information about within individual variability and what predictors determine the outcome variable of interest (Bolger et al., 2003). This approach enables researchers to examine events as they occur in participants' naturalistic environments and to explore the correlates, predictors and outcomes of interest in real-life time (Shiffman et al., 2008, Piasecki et al., 2007).

The EMA electronic diary approach can be interval, signal and event contingent protocol for diary data collection (Bolger et al., 2003). An interval contingent design requires participants to record their self-report at predetermined intervals. Signal contingent data collection prompts the participant by a signalling device (i.e. an audio prompting device) to provide a diary report at fixed or random time intervals. Event contingent protocols are based on particular incidents of interest whereby participants complete a self-report each time an experience of interest

occurs. In order to facilitate reliable and valid data, the participant must be committed and dedicated to complete the full electronic diary (i.e. several times over the course of a day, for a total of one month). This, in turn, places a substantial demand on the participant because of repeated audio prompts for data collection (Piasecki et al., 2007).

Little is known about the effect of completing the electronic diary on the respondents' experiences. Electronic diary approaches may be exposed to several methodological complexities, namely: reactance, habituation, increased complexity and gradual entrainment (Bolger et al., 2003). Reactance occurs when the participant's behaviour changes as a result of completing the diary. A reactive measure is one that changes the phenomenon it is designed to assess. This is desirable if measurement occurs as part of an intervention aimed at changing behaviour, but is problematic when measurement over time is used only to assess the phenomenon of interest. Several studies have tested the reactivity of the EMA diary in participants with chronic pain (Aaron et al., 2005, Stone et al., 2003c, Cruise et al., 1996) and alcohol abuse (Litt et al., 1998) (see table 4.1 for examples of reactivity studies).

Table 4.1 Studies measuring reactivity of diaries

Author, year/country	Aim	Study: operational definition of reactivity	Participants	Methods	Findings
Aaron et al., (2005) USA	Examine reactivity in repeated measures electronic diary for pain.	Testing for average change in pain over time	N=71 participants with chronic temporomandibular pain **Demographics**: N=71 female (86%), age 38 years, SD 12, white 93%.	Daily electronic diary Palm OS: 2 weeks, 3 daily data entries audio prompted at predetermined times by participants. Compensation payment for adherence to data collection protocol.	Response rate approx 91% for N=71. Diary was not reactive based upon the non-significant change over time in pain scores. Subjective participant reports assessed using study feedback questionnaire identified approximately 75% of participants reported the electronic diary affected their pain, affected their daily activities (50%), their mood (39%) and their beliefs about their pain.
Stone et al., (2003) USA	Examine reactivity in repeated measures electronic diary for pain.	Testing for average change in pain over time	N=91 participants with chronic pain **Demographics:** Sample primarily white, female, married. Means range: 49.0 to 53.5 years	Daily electronic diary Sony Clie: 4 groups: A: control no EMA (n=23), B: 3 entries per day (n=23), C: 6 entries per day (n=22), D: 12 entries per day (n=24), all for 14 days. Audio prompted. Compensation payment for adherence to data collection protocol.	Diary was not reactive based upon the non-significant change over time in pain scores in relation to the frequency of data collection. Significantly different response rates for the 3 EMA groups but overall compliance rates high. 12 entries per day reported the most burden form the EMA schedule compared to the other 2 EMA groups.
Cruise et al., (1996) USA	Examine reactive effects of repeated measures wristwatch and paper diary	Testing for average change in pain and mood over time	N=35 participants with rheumatoid arthritis **Demographics**: 10 men and 25 females, mean age 52.4, SD 12.3, predominantly married and well educated	Pre-programmed wrist-watch (Seiko RC-4000 Wristmac) and paper diary. 1 week, 7 daily audio prompts to signal data collection 8am – 9 pm	Diary was not reactive based upon the non-significant change over time in pain scores or mood scores in relation to the frequency of data collection
Litt et al., (1998) USA	Examine reactive effects of repeated measures wristwatch and paper diary in alcohol-depended men	Testing for average change in alcohol intake and abstinence days	N=27 men with alcohol dependency Demographics: mean age 46.6 years, SD 7.8, 33% married	Pre-programmed wristwatch and paper diary. 1 week, 8 daily signals 8am -10pm. Compensation payment for adherence to data collection protocol	Diary was not reactive based upon non-significant change over time in the number of days drinking and abstinence in relation to the frequency of data collection. 70% of men reported the EMA approach made them aware of the drinking problems and therefore made them drink less

Reactivity of the EMA approach has been examined using both paper-based (Litt et al., 1998, Cruise et al., 1996) and electronic-based (Aaron et al., 2005, Stone et al., 2003a) approaches which did not find any reactive effects of the EMA approach (see table 4.1). There are a number of methodological limitations which featured in each of the studies. Participants who used a paper-and-pencil recording diary may have fabricated their answers by forward and backfilling their diaries, and may have introduced retrospective memory recall (Litt et al., 1998, Cruise et al., 1996). Cruise's study had 50% missing data in the participants' paper-based diaries and, therefore, was at risk of a type two statistical error; for example, believing that pain levels did not change over time, when, in fact, pain levels may have changed. Lastly, both of the studies that included paper-based EMA approaches had small study samples (Cruise N=35 and Litt N=27) and that, therefore, limits the generalisabilty of their study findings because the participants were not representative of the wider population.

For the electronic diary studies (Aaron et al., 2005, Stone et al., 2003a) they were biased in favour of white females, and this sample therefore limits the generalisabilty of the findings to men and to people from different ethnic groups. It is possible that reactive effects of the EMA approach may have been masked by the study designs. Across the four reviewed studies (Aaron et al., 2005, Stone et al., 2003a, Cruise et al., 1996, Litt et al., 1998), data collection was limited to either 1 week or 2 weeks and these durations may not have been long enough to detect reactive effects. The salient and chronic nature of pain and alcoholism in the study samples may have produced reactive effects earlier in the course of their illnesses. In other words, participants may have been "informally" monitoring their pain levels and cravings for alcohol for some time, so reactive effects would have already taken place. Three studies (Litt et al., 1998, Aaron et al., 2005, Stone et al., 2003a) used payment as an incentive for adherence to the study protocol. Payment may have influenced response rates and the potential of reactive effects.

Finally, it is important to acknowledge the limitations of the operational definition of reactivity. Commonly, a lack of reactive effect for daily pain scores and alcohol intake was defined by the absence of any statistically significant change in the

variable of interest over time (Aaron et al., 2005, Stone et al., 2003a). Using such criteria is problematic for a number of reasons to evaluate reactivity to the EMA diary. If a significant change in pain scores was observed within the reviewed studies, the assumption that the change was due to reactivity is questionable. Patients' pain can change due to a number of factors, including regression to the mean (Bowling, 2002), treatment modifications, and altered health states over time. Testing reactivity in this way assumes that reactivity is a gradual build-up of the effect of the EMA diary, whereas reactive effects may happen on the first day of data collection and subsequently remain unchanged. Importantly, all of the reviewed studies measured reactivity as a gradual change in average scores of the variable of interest over time. In addition, reactivity could be observed as a change in associations between two or more variables over time. This relationship was not assessed.

A further key limitation to Aaron, Litt and Cruise's studies was the lack of a control group and, therefore, the findings are treated with caution. In the absence of a comparison group, it is impossible to know how changes in the variables of interest would have been affected without the EMA approach. None of the reviewed studies identified any statistically significant reactive effects; however, due to a number of limitations which featured in each study, the findings are treated with caution.

Subjective reports were assessed using a study feedback questionnaire and a debriefing interview at the end of data collection (Aaron et al., 2005, Litt et al., 1998). Aaron identified that 75% of the study participants reported that the electronic diary affected their pain, daily activities (50%) and their mood (39%). In addition, Litt and colleagues identified that 70% of men identified that the EMA approach made them more aware of their drinking problem and, therefore, made them drink less. Both studies identified that the EMA process may have been reactive but the statistical results indicate otherwise, because the quantitative findings failed to reach statistical significance. The subjective reports may have been affected by retrospective memory recall. There are a number of problems with the evidence base for reactivity of the EMA approach. It is unlikely that reactivity would threaten the validity of this method, but additional research

would useful for different patient groups, in particular, people affected by cancer, given the context of this research.

A further consideration to the EMA approach is habituation. Habituation has been described as the development of habitual responses when completing the diary, that is to say, a tendency to skim over questions that rarely apply to the participants' experience (Bolger et al., 2003). To date, no research has explored the influence of habituation on diary data collection and remains unknown. Repeated exposure to diary questions over time may change participants' understanding of a particular construct, in particular, increased complexity and gradual entrainment (Bolger et al., 2003). Increased complexity refers to the development of a more advanced understanding of a particular construct as a result of repeated exposure to the surveyed domain, whereas, gradual entrainment has been described as participants changing their conceptualisation of their illness to fit with those measured in the diary. Bolger and colleagues have suggested such complexities are possible, but to date, no study has formally tested for increased complexity or gradual entrainment in diary studies. In summary, there is very little evidence to support that the complexities acknowledged in the aforementioned occur in the participant experience, or pose a threat to the diaries validity (Suedfeld and Pennebaker, 1997, Thomas and Diener, 1990).

The EMA electronic diary has not been applied to men with prostate cancer and therefore, recruitment and compliance rates for the EMA electronic diary are unknown for this patient group. A potential strategy to test the feasibility of this method and to assess change over time is to use single-case studies (n of 1) (Borckardt et al., 2008, Molenaar, 2004, Crane et al., 2003). Single-case designs have been described as a repeated-measure design in which a single participant is observed over time, whereby the individual serves as their own control and a number of observations are taken over a set period of time (Lillie et al., 2011). Single-case studies are also commonly known as N-of-1. Single-case studies (N-of-1) enable researchers to monitor behaviour change over time. Usually the participant is monitored though the use of a daily diary to test the relationships between independent and dependent variables of interest (Hadert and Quinn,

2008). This design requires a very small number of participants but enables assessment of an "individual" and how variables of interest changes over time, and reduces retrospective memory recall. The value of this design has enabled a better understanding of symptom management (Crane et al., 2003) and has been applied to cancer research (Bruera et al., 1992), albeit not prostate cancer patients specifically.

To address the aim of this Ph.D. study, an EMA adapted/n-of-1 design was conducted to assess change over time, and test the social support theoretical model (Cohen et al., 2000) within individuals. The rationale for the EMA adaption in the current study was based on a number of important factors. The EMA method has not been applied to this patient group, and therefore there were a number of unknown factors, and these include: a) agreement to complete the diary, and b) participant adherence to data collection protocol.

The innovative EMA adapted/N-of-1 design has the potential to expanded empirical reach to capture patient experience as it unfolds in real time, and would enable the social support theoretical model (Cohen et al., 2000) to be tested within individuals (Molenaar, 2004). The EMA adapted/N-of-1 study aimed to overcome some of the problems associated with the prospective longitudinal survey. The complementary methodology aimed to understand change over time based on group level effects, and within the individuals (Bolger et al., 2003). Ultimately, the researcher considered the complementary methodology offered a broad, rich and in-depth understanding that would contribute to a better knowledge of men's experiences of social support, coping and self-management in relation to physical and psychological well-being.

The following chapter identifies the research aim, research questions and the methods chosen for the prospective, longitudinal survey and the EMA adapted/N-of-1 studies to address the questions. The planned analysis, and data screening and cleaning in preparation for statistical analysis are also described.

4.3 Aim of the study

The aim of this Ph.D. study was to test the mechanism effect of coping and social support on HRQoL between individuals and within individuals affected by prostate cancer. This Ph.D. also aimed to identify the self-management behaviours of men affected by prostate cancer over time.

4.4 Research questions

To meet the aim of the study, specific research questions were informed and justified by the findings from the structured literature reviews in chapters 1, 2, and 3:

Questionnaire survey

1. Approximately 1 month after a prostate cancer diagnosis, this study will examine the following question. What is the relationship between demographic (age, socio-economic status, educational level) and clinical (staging, PSA, Gleason Score and treatment) variables in men affected by prostate cancer and the following:

a) coping,

b) social support,

c) health-related quality of life,

e) anxiety and depression,

e) self-efficacy,

f) stress,

g) self-management?

2. How does the following change between recruitment 1 month after diagnosis (time 1) and 7 months after diagnosis (time 2):

a) coping,

b) social support,

c) health-related quality of life,

e) anxiety and depression,

e) self-efficacy,

f) stress,

g) self-management?

3. Controlling for baseline (time 1; 1 month after diagnosis) characteristics/variables, does social support (perceived, received and satisfaction level) moderate/mediate the relationship between coping and a) anxiety, b) depression, c) health-related quality of life, at time 2 (7 months after diagnosis)?

EMA adapted/N-of-1 (electronic behavioural diary)

In men affected by prostate cancer:

1a. Which patient characteristics influence agreement to complete the EMA adapted/N-of-1 data?

1b. What are the response rates of participants filling in a diary over several weeks?

2a. What are the daily self-management behaviours in real time and do they change over time?

2b. What are the daily social supportive experiences in real time and do they change over time?

2c. Do social supportive experiences have a main effect, or do they moderate/mediate the relationship between coping and mood in real time?

4.5 Theoretical framework

The stress buffering model (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984, Cohen and Hoberman, 1983) was considered appropriate as the theoretical framework for this study because it enabled main/moderation/mediation effects of social support, coping, and physical and psychological well-being to be tested. This theoretical model suggests that these effects exist. Chapter 2 demonstrated that social support has been found to be a predictor of HRQoL, but little is known about the mechanisms through which social support operates with coping and HRQoL in prostate cancer survivors, that is to say, main/moderation/mediation effects. The analysis will test the prediction of this framework (Cohen et al., 2000) for main/moderation/mediation effects of social support and coping on physical and psychological well-being in prostate cancer survivors. This model has been tested in participants with long-term conditions (Pereira and Canavarro, 2009, Newsham, 1998, Doeglas et al., 1994) and in cancer (Gremore et al., 2011, Carpenter et al., 2010, Kroenke et al., 2006), however, this

model has been researched in prostate cancer to a much lesser extent. Testing this model between and within prostate cancer survivors was hoped to advance the current evidence base. The theoretical framework includes several components that were of particular interest in this study, namely: social support, coping, and physical and psychological well-being (see figure 4.1 for theoretical model).

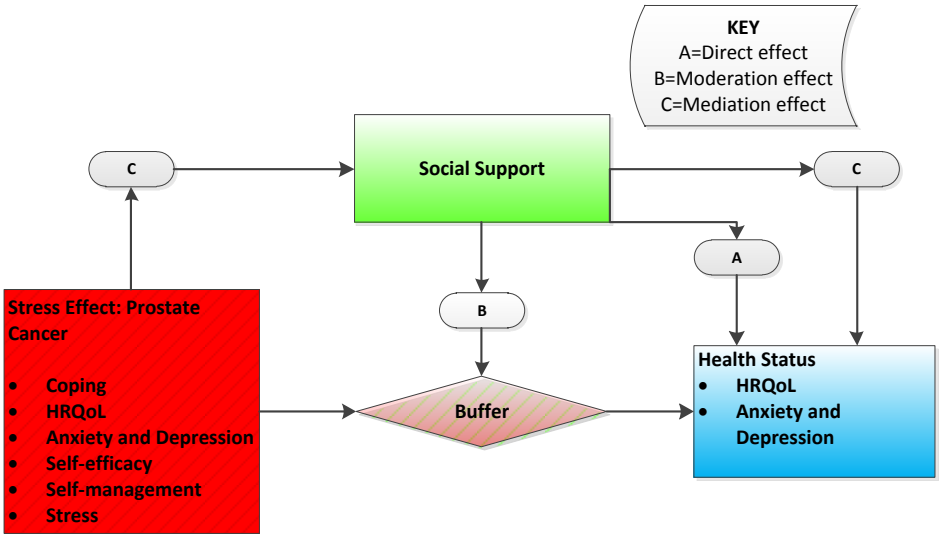


Figure 4.1 Stress Buffering Model – Study Model

4.5.1 Participant characteristics

This study was designed to recruit men diagnosed with prostate cancer (of all stages and treatments) at approximately 1 month after diagnosis but before treatment from 2 teaching hospitals (Ninewells Hospital and Perth Royal Infirmary) in Scotland. Recruitment took place between April 2010 and March 2011. Inclusion criteria included patients over 18 years of age, with an awareness of their cancer diagnosis, before receiving treatment for their prostate cancer and able to give informed consent. Exclusion criteria were those patients identified by their clinical care team to be physically or psychologically unfit to take part in the study, and therefore unable to give informed consent.

4.5.2 Prospective survey sample size calculation

A power analysis was conducted using the software package G*Power (G*Power, 2008). This calculation assumed effect size (f^2) of 0.15 (a medium effect size) (Petrie and Sabin, 2005), alpha level of 0.05, and power of 0.80, and the number

of predictors as 10. The software package calculated the optimum sample size as 90. Given that there were 230 new prostate cancer patients in NHS Tayside each year (on the advice from staff at the clinical site where the research was being conducted), it seemed reasonable to assume that it would be possible to recruit 108 patients (over a one-year period) to the study, which would allow for some attrition given the nature of the longitudinal design. However, the actual number of men diagnosed with prostate cancer during the recruitment phase of this research was considerably less than previously advised by clinical staff. To ensure that each regression analysis was powered sufficiently, the researcher used the following power calculation equation: N=50 + 8m (where m is the number of independent variables) as detailed in chapter 5.

4.6 Prospective, longitudinal survey

4.6.1 Methods of the prospective, longitudinal survey

In relation to the research questions, the questionnaire survey was used to assess 1) the relationship between demographic and clinical variables with self-efficacy, coping, social support, stress, self-management, anxiety and depression and HRQoL, 2) evaluate changes in self-efficacy, coping, social support, stress, self-management, anxiety and depression and HRQoL, at approximately 1 month after diagnosis and 7 months follow-up, and 3) to test whether social support has a main effect, or whether social support moderates/mediates the relationship between coping and a) anxiety, b) depression, and c) HRQoL. Participants completed the questionnaire survey at approximately 1 month after diagnosis (before treatment) and approximately 7 months after diagnosis.

4.6.2 Socio-demographic variables

Date of birth was obtained from medical records and confirmed with the patient. Marital status, education and employment were obtained verbally from the participant. Deprivation was assessed using the Scottish Index of Multiple Deprivation (SIMD) (Scottish Government, 2009). The SIMD combines 38 indicators across 7 domains, namely: income, employment, health, education, skills and training, housing, geographic access and crime. Scores are calculated using postcodes and represents a “relative” measure of deprivation in any one

geographical area. The term "relative" means, for example, that the index can tell if an area is more or less deprived than another area, *but* not by how much, and it will not determine individual deprivation. The SIMD compares geographical areas from the most deprived (rank 1) to the least deprived (rank 6,505) data zones. Commonly, quintiles (20%) are used to determine wider concentrations of deprived areas in Scotland (see table 4.2).

Table 4.2 SIMD rank

	SIMD Rank	
Quintile (20%)	**From**	**To**
1	1	1301
2	1302	2602
3	2603	3903
4	3904	5204
5	5205	6505

The scores formed a categorical variable with five categories (one being the most deprived to five being the least deprived). For full methodology of the SIMD, see the SIMD technical report (Office of the Chief Statistician, 2009). Age, marital status, education, employment and deprivation variables were used to describe the sample and to address the research questions. These variables were also important to identify bias for agreement to complete the electronic behavioural diary, in addition to assess section bias (using age variable only, due to NHS ethics restrictions for confidentiality of the patients) and attrition bias.

4.6.3 Clinical variables

Cancer stage, PSA, Gleason score, treatments and co-morbidity were collected from medical records. These variables were used to describe the sample and to identify bias for agreement to complete the electronic behavioural diary, and those who did not, in addition to assess attrition bias and selection bias (using cancer stage and treatment only, due to NHS ethics restrictions for confidentiality reasons).

4.6.4 Questionnaire instruments

Perceived Stress Scale (PSS) (Cohen et al., 1983)

The Perceived Stress Scale (PSS) is a 10-item questionnaire commonly used for measuring the perception of stress. The items are designed to measure how unpredictable, uncontrollable, and overloaded respondents find their lives; in

particular, it measures the perceived degree to which environmental demands exceed abilities to cope (Cohen et al., 1983) in the past month. The instrument is easy to understand and takes minutes to complete (Cohen and Williamson, 1988). Respondents are asked to report their thoughts and feelings during the past month. The PSS has been widely applied to clinical settings: meningitis (Burns et al., 2002), respiratory tract infections (Fondell et al., 2011), bacterial vaginosis in human pregnancy (Harville et al., 2007, Culhane et al., 2001), wound healing (Ebrecht et al., 2004), skin disorders (Garg et al., 2001), interstitial cystitis (Gottsch et al., 2011), survivors of suicide (Mitchell et al., 2008) and prostate cancer (Stone et al., 1999). Internal reliability has been demonstrated using the Cronbach's alpha statistic 0.87 in prostate cancer participants (Stone et al, 1999). Validity has been demonstrated with significant correlations found in poor diabetic control of blood sugar levels (Surwit et al., 2002). The scoring of the PSS are obtained by reverse scoring the responses (e.g. 0=4, 1=3, 2=2, 3=1, 4=0) to the four positively weighted questions (items 4, 5, 7 and 8) and then adding together all the scores across all the items. No normative data are available for the PSS in prostate cancer respondents; however, normative data are available within a non-clinical sample of 2,387 respondents in the United Stated (Cohen, 1994) see table 4.3.

Table 4.3 Norm Table for the PSS 10-item questionnaire

Category	N	Mean	S.D.
Gender			
Male	926	12.1	5.9
Female	1406	13.7	6.6
Age			
18-29	645	14.2	6.2
30-44	750	13.0	6.2
45-54	285	12.6	6.1
55-64	282	11.9	6.9
65 & older	296	12.0	6.3
Race			
White	1924	12.8	6.2
Hispanic	98	14.0	6.9
Black	176	14.7	7.2
Other minority	50	14.1	5.0

Berlin Social Support Scale (BSSS) (Schulz and Schwarzer, 2003)

This 38-item questionnaire was developed for the study of social support in cancer participants (Schulz and Schwarzer, 2003). This instrument has a multidimensional design that assesses the following constructs: perceived social support (item

numbers 1-8), received social support (item number 24-38), need for support (item numbers 9-12), support-seeking (item numbers 13-17), protective buffering (item numbers 18-23) and satisfaction level (item number 38) with social support in the past month. The authors of this questionnaire have not defined what is meant by "protective buffering" and this scale includes the following items: *I kept all bad news from her/him, I avoided everything that could upset, her/him, I showed strength in her/his presence, I did not let him notice how bad and depressed I felt, I avoided any criticism, and I pretended to be very strong, although I did not feel that way.* The BSSS has been applied to clinical settings in the following patient groups: depression (Wojtyna et al., 2007), HIV (Luszczynska et al., 2007b), stem cell transplantation (Herzberg et al., 2010), prostate cancer participants (Scholz et al., 2008) and mixed cancer sites (Boehmer et al., 2007, Luszczynska et al., 2007a, Luszczynska et al., 2005). The Cronbach's alpha statistics for the subscales are as follows: perceived social support 0.83, received social support 0.83, need of support 0.63, seeking support 0.81, protective buffering 0.82. Validity has also been identified in a number of studies (Scholz et al., 2008, Schulz and Schwarzer, 2003). The respondents rate their agreement level with statements on a four-point rating scale (1 strongly agree, 2 somewhat agree, 3 somewhat disagree, and 4 strongly disagree). Negative items (items 4, 5, 6, and 12) are reversed-scored. Scale scores are generated by calculating a mean score. No normative data are available for the BSSS questionnaire.

Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)

This 14-item questionnaire assesses anxiety (7 items) and depression (7 items) (Snaith and Zigmond, 1988, Snaith and Zigmond, 1986, Zigmond and Snaith, 1983) in non-psychiatric patients. This measure asks respondents to report how they have being feeling in the past week. An exploratory factor analysis of the HADS was carried out on 568 newly diagnosed cancer participants by Moorey et al. (1991). Reliability has been demonstrated for the anxiety and depression scales, with Cronbach's alpha at 0.93 and 0.90, respectively. Validity of this measure has been identified in a number of cancer studies, including prostate cancer studies (Jadhav et al., 2010, Zenger et al., 2010, Nelson et al., 2009, Avery et al., 2008, Gerbershagen et al., 2008, Burnet et al., 2007, Brindle et al., 2006, Bisson et al., 2002). Each item is scored from 0 to 3, so the total score ranges from 0 to 21 for both of the subscales. Higher scores indicate greater anxiety and depression. A score of 8 – 10 on each

subscale would indicate the possibility of anxiety and depression, whereas a score of 11 and above would indicate probable anxiety and depression. The HADS is a screening measure of possible anxiety and depression and actual cases of anxiety and depression would have to be confirmed by a clinical psychiatrist. In a sample of 568 newly diagnosed cancer participants, Moorey et al., (1991) found a mean score for the anxiety and depression subscale scores of 5.44 (SD 4.07, range 0-19) and 3.02 (SD 2.98, range 0-15) respectively.

Mental Adjustment to Cancer Scale (MAC Scale) (Watson et al., 1988a)

This 40-item questionnaire provides an assessment of participants' "psychological adjustment" (coping response) to the diagnosis of cancer. It is an instrument developed specifically for the assessment of coping styles in cancer participants. This instrument is internationally used and widely implemented in cancer studies; mostly breast cancer (Carlsson et al., 2005, Inoue et al., 2003, Okano et al., 2001, Osborne et al., 1999, Schnoll et al., 1998), but also in other cancer groups, namely: lung cancer (Mulcare et al., 2011, Uchitomi et al., 2003), laryngeal cancer (Johansson et al., 2011) and prostate cancer (Couper et al., 2010, Shields et al., 2004). It has five subscales: fighting spirit, helpless/hopeless, anxious preoccupation, fatalistic, and avoidance. The number of items in each subscale and score ranges are detailed in table 4.4 below:

Table 4.4 Subscale item break down for the MAC scale

Subscale	Item numbers	Number of items	Possible range of scores
Fighting spirit	4, 5, 6, 11, 13, 16, 18, 20, 26, 27, 28, 31, 32, 34, 39, 40 2, 9, 17, 23, 25, 36	16	16-24
Helpless/Hopeless	2, 9, 17, 23, 25, 36	6	2-24
Anxious preoccupation	1, 3, 10, 14, 19, 21, 22, 29, 37	9	9-36
Fatalistic	7, 8, 12, 15, 24, 30, 33, 35	8	8-32
Avoidance	38	1	1-4

Internal reliability has been demonstrated with Cronbach's alpha results for fighting spirit at 0.84, anxious preoccupation at 0.65, fatalistic at 0.65, and helpless/hopeless at 0.79, with good test-retest reliability (Watson et al., 1988a). More recently, the psychometric properties of the MAC scale have been revisited in a varied sample of cancer participants (Watson and Homewood, 2008) and the original five styles of coping can be subsumed to provide two factors of positive adjustment (item numbers: 4, 6, 11, 12, 13, 15, 16, 18, 20, 26, 27, 28, 31, 32, 34, 39, 40) and negative adjustment (item numbers: 2, 3, 7, 9, 14, 17, 21, 22, 23, 24, 25, 30, 35, 36, 37, 38) scores for general analysis requirements with demonstrated reliability at 0.84 and 0.84, respectively. Validity of this measure has been identified through significant correlations with the HADS (Watson and Homewood, 2008, Greer et al., 1989). The respondents rate their agreement level with statements on a four-point rating scale (1 definitely does not apply to me, 2 does not apply to me, 3 applies to me, 4 definitely applies to me) for how they are feel at present. Score are calculated for each subscale and indicate the extent to which a particular coping style is being used. The new 2 factor cut-off points (positive and negative adjustment) were tested in 1255 patients with various cancer diagnoses and the reference scores are detailed below:

Table 4.5 MAC scale scores for positive and negative adjustment

	Negative adjustment	Positive adjustment
Statistics		
N	1148	1156
Valid missing	112	104
Mean	29.37	54.06
Std. Deviation	6.81	6.74
Range	37.00	49.00
Minimum	16.00	19.00
Maximum	53.00	68.00

Self-care self-efficacy Scale (SE Scale) (Schwarzer and Jersualem, 1992)

This 7-item questionnaire measure allows the evaluation of general beliefs in one's ability to respond to and control environmental demands and challenges. This is the belief that one can perform a novel or a difficult task, or cope with adversity in various domains of human functioning. The general self-efficacy measurement has

good reliability from 23 nations, with Cronbach's alpha ranging from 0.76 - 0.90 with good test-retest reliability (Schwarzer and Jerusalem, 1995). Previous cancer studies have used the SE Scale for general self-efficacy beliefs (Boehmer et al., 2007, Luszczynska et al., 2005). The SE scale is designed to assess generalised self-efficacy beliefs (Schwarzer and Jerusalem, 1992); however, Bandura (1997) proposed that self-efficacy should be measured in the context of the specific task to be performed. He argues that generalised measures of self-efficacy lack specificity and sensitivity (Bandura, 1997). General measures do not provide an assessment of the specific task or context of one's belief or confidence to perform a particular behaviour (Bandura, 1997). The SE Scale (Schwarzer and Jersualem, 1992) was modified to encompass a specific self-care self-efficacy measure for the context of this study, the scores range from a minimum of 1 to a maximum of 4. No normative data exists for this questionnaire.

EORTC Quality of Life (QLQ C30) Prostate module (PR25) (Aaronson et al., 1993)

This 30-item questionnaire is an integrated measurement system for health-related quality of life (HRQoL) in cancer participants. This is an internationally-recognised instrument developed over ten years, and has been used in more than 2200 cancer studies (Fayers et al., 2001) and, specifically, prostate cancer studies (Galvao et al., 2010, Queenan et al., 2010, Berglund et al., 2007, Culos-Reed et al., 2007, Augustin et al., 2002). It evaluates the following functional scales: physical, role, emotional, cognitive and social; symptoms: fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite lose, constipation, diarrhoea; financial difficulties; and global health status/quality of life. The number of items in each subscale and the score ranges are detailed in table 4.6.

Table 4.6 Subscale item break down for the EORTC C30

	Number of items	Item range*	Item numbers
Global health status/quality of life			
Global health status/QOL	2	6	29, 30
Functional scales			
Physical functioning	5	3	1 to 5
Role functioning	2	3	6, 7
Emotional functioning	4	3	21 to 24
Cognitive functioning	2	3	20, 25
Social functioning	2	3	26, 27
Symptom scales / items			
Fatigue	3	3	10, 12, 18
Nausea and vomiting	2	3	14, 15
Pain	2	3	9, 19
Dyspnoea	1	3	8
Insomnia	1	3	11
Appetite loss	1	3	13
Constipation	1	3	16
Diarrhoea	1	3	17
Financial difficulties	1	3	28

*Item range is the difference between the possible maximum and the minimum response to individual items; most items takes values from 1 to 4, giving a range =3
(Fayers et al., 2001, p.7)

Respondents are asked to report scores in the past week. Internal reliability for the subscales has been identified from 0.70 to 0.90, and validity has also been reported (Aaronson et al., 1993). A high score in HRQoL represents *high HRQoL,* but a high score for symptoms scale represents a *high level of symptomatology.* Normative data is detailed in table 4.7 for a heterogeneous sample (all prostate cancer stages).

Table 4.7 Normative data for EORTC C30

Constructed scales	Mean	(SD)	Median	IQR
Global health status/quality of life				
Global health status/QOL	68.4	(22.2)	66.7	[50-83.3]
Functional scales				
Physical functioning	80.2	(25.6)	93.3	[66.7-100]
Role functioning	82.7	(28.2)	100	[66.7-100]
Emotional functioning	76.6	(23)	83.3	[66.7-100]
Cognitive functioning	83.2	(20.8)	83.3	[66.7-100]
Social functioning	80.2	(27.2)	100	[66.7-100]
Symptom scales / items				
Fatigue	26.9	(26.6)	22.2	[0-44.4]
Nausea and vomiting	5.1	(14.2)	0	[0-0]
Pain	23.3	(30.3)	0	[0-33.3]
Dyspnoea	16.8	(25.7)	0	[0-33.3]
Insomnia	24.5	(30.5)	0	[0-33.3]
Appetite loss	10.4	(23.6)	0	[0-0]
Constipation	14.6	(27.2)	0	[0-33.3]
Diarrhoea	8.4	(19.4)	0	[0-0]
Financial difficulties	9.0	(21.5)	0	[0-0]

(Scott et al., 2008, p.268)

The Prostate Model for the EORTC Quality of Life (QLQ C30) tool (PR25) was used in this thesis to assess disease-specific HRQoL. It is a 25-item questionnaire designed for use among participants with localised, locally advanced and metastatic prostate

cancer. The subscales assess urinary symptoms, bowel symptoms, treatment-related side-effects and sexual functioning and are detailed in table 4.8.

Table 4.8 Subscale item break down for the EORTC PR25

	Number of items	Item range*	Item numbers
Functional scales			
Sexual activity	2	3	20, 21
Sexual functioning	4	3	22-25
Symptom scales			
Urinary symptoms	8	3	1, 7, 9
Bowel symptoms	4	3	10-13
Hormonal treatment-related Symptoms	6	3	14-19
Incontinence aid	1	3	8

*Item range is the difference between the possible maximum and the minimum response to individual items; most items takes values from 1 to 4, giving a range =3
(van Andel, et al., 2008)

The PR25 questionnaire was tested in a cross-cultural sample of cancer participants in 13 countries to confirm hypothesized scale structure, and demonstrates acceptable psychometric properties and clinical validity, and internal reliability ranges from a low of 0.70 to a high of 0.86 (van Andel et al., 2008). Currently, there are no normative data available for the PR25.

Self-care Log (SCL) (Dodd, 1982)

This questionnaire measures self-care activities for cancer participants and has been predominately used in the study of side-effects and self-care following radiotherapy and chemotherapy (Wilson et al., 2010, Kidd et al., 2008, Wong et al., 2006, Borthwick et al., 2003, Schumacher et al., 2002, Richardson and Ream, 1997, Dodd, 1997, Foltz et al., 1996, Nail et al., 1991, Dodd, 1982). Drawing on the work of previous research (Wilson et al., 2010, Dodd, 1997, Nail et al., 1991, Dodd, 1982), the questionnaire used consisted of 1) the major complaint: urinary, bowel, sexual dysfunction, other; 2) self-care actions taken; 3) effectiveness of the action, and 4) the sources of suggestions for self-care, see table 4.9 for subscale overview.

Table 4.9 Subscale break down for the self-care log

Subscale	Item numbers	Number of items	Possible range of scores
Major Complaint			
Urinary	1	1	0-1
Bowel	2	1	0-1
Sexual	3	1	0-1
Other	4a-4b	2	0-1
Self-care actions			
Urinary	1a-1o	15	0-15
Bowel	2a-2r	18	0-18
Sexual	3a-3o	15	0-15
Other	4aa-4ae, 4bf-4bj	10	0-10
Effectiveness of self-care actions			
Urinary	1a-1o	15	0-5
Bowel	2a-2r	18	0-5
Sexual	3a-3o	15	0-5
Other	4aa-4ae, 4bf-4bj	10	0-5
Self-care suggestions	5	8	0-8

Content validity of the prostate self-care log was established though discussions with prostate cancer patients and cancer healthcare professionals at NHS Tayside, where this research was being conducted. No normative data was available for the self-care log.

4.6.5 Procedures

Recruitment procedure

1. Ethics and Research and Development approval was granted for this study (10/S1402/7). The researcher acted in accordance with the regulations of the ICH Good Clinical Practice guidelines.
2. See appendices 4.1 to 4.9 for study documentation (participant information sheet, consent form, letters, and survey).

- All patients meeting the inclusion criteria were identified from NHS Tayside Urology Multi-disciplinary Team (MDT) Meetings. All new prostate cancer patients within NHS Tayside are discussed at this MDT meeting.
- An introductory letter, Patient Information Sheet (PIS) and suggested time of appointment were sent to patients who met the inclusion criteria.

The option for an alternative date and time was included in the reply form.

- Potential participants were given a minimum of 24 hours to consider their participation in the research to ensure informed consent.
- At the appointment, the researcher checked with the patient that they read and understood the PIS, any questions were answered by the researcher and explanations were provided to ensure informed consent. Participants willing to take part in the study were asked to sign a study consent form.
- Consenting participants were given a copy of the signed consent form; one copy was filed in the study master file and one copy was filed in the patient's medical notes.
- A letter was sent to the participant's General Practitioner (GP) informing them of their patient's participation in the study. The GP was sent the researcher's contact details in case the GP wanted to discuss their patient's participation in the study.

Data Collection Procedure - Prospective Longitudinal Survey

- Clinical data (PSA, cancer stage, treatment, Gleason Score and co-morbidities) were obtained from medical records and demographics (date of birth, education, marital status, and employment) were obtained verbally from the participant.
- The questionnaire survey data were collected at two time points: time 1 (after consent [before treatment at approximately 1 month after diagnosis]), and time 2 (6 months follow-up). Participants were given a stamped addressed envelope for the return of the questionnaire at time 1 and time 2. A 14-day questionnaire reminder letter was sent to participants at time 1 and time 2 if the questionnaire was not returned to the researcher within 14 days of them having received the questionnaire.
- Basic demographics (age, cancer stage and treatment, and reason for non-participation) were collected for the non-recruits to provide a comparison between recruits and non-recruits.

- All participants were given a unique study number and all data were securely stored in a locked filing cabinet, in a locked room at the University of Dundee. Electronic data were held on a secure University network, with access via a password-protected PC.

4.6.6 Ethical considerations

Participants identified as being at risk of having anxiety and depression (HADS score ≥11) had their GP notified by letter. This step was necessary in order to provide a duty of care to the patient. Participants gave their informed consent on the study consent form to enable the researcher to notify their GP. The researcher also notified the patient of their results by telephone when the HAD score was ≥11.

4.6.7 Statistical analysis (prospective longitudinal survey)

Data were double-entered into SPSS version 17.0 to check for discrepancies in the data set (Bowling, 2002). Prior to the analysis, variables were examined for accuracy of data entry, missing values and the assumptions of the proposed analysis. This verification was done through traditional exploratory analysis (Tabachnick and Fidell, 2007). Normality distributions of the variables were checked by statistical and graphical methods. Skewness and Kurtosis significance values were assessed using the Kolmogorov-Smirnov (K-S) test and a histogram was plotted for each variable. Appropriate transformations (Tabachnick and Fidell, 2007) of the variables were performed to reduce skewness, kurtosis, the impact of outliners, and to improve normality, linearity and homoscedasticity. To address the research questions, statistical analysis was performed using parametric tests (Pearson Product Moment Correlations, t-tests, repeated measures ANOVA and multiple regression analyses).

Internal reliability of the measures (HADS, EORTC C30, PR25, MAC scale, SE Scale, PSS, SCL, BSSS) was evaluated using Cronbach's alpha statistic (Tabachnick and Fidell, 2007, Field, 2005).

4.7 EMA adapted/N-of-1

4.7.1 Electronic diary development

The EMA adapted/N-of-1 methodology has not been applied to prostate cancer participants before and, therefore, the electronic diary had to be developed. The researcher convened a Ph.D. Steering Group (service users [men with prostate cancer], clinicians and research supervisors) to inform the development of the electronic diary (see appendix 4.10 for an example of the Steering Group documentation). Informed guidance was essential for the diary development, as the EMA adapted/N-of-1 method is extending the field in this patient group. In addition to the advice and comments from the steering group, there was an extensive pilot phase of the diary.

The pilot was a two-phase process; “phase 1” involved 11 electronic diary pilots among colleagues and acquaintances, with “phase 2” consisting of 3 electronic diary pilots directly involving men with prostate cancer. The pilot enabled the researcher to resolve any technical issues and systematically gather feedback on the contents and scheduling of the diary (see appendix 4.11 for the results of the pilot).

4.7.2 Scheduling of EMA Adapted/N-of-1 data collection

For case-based time series analysis, a minimum of 30-60 data points are needed (Borckardt et al., 2008). To account for missing data, the current study aimed to capture 90 data points. Each participant collected data for 1 month prompted by audio alarm to complete the diary at 3 pre-determined intervals per day (totalling 90 data points). In addition, the participants could complete an incident entry at any time throughout the 1-month period. The timings of the data collection were determined by the participants’ lifestyle, for example, sleeping and waking times, and employment commitments. The data collection timings were at equally-spaced time intervals throughout the day, for example, at 8am, 2pm, and 8pm, and 9am, 3pm, and 9pm. The “snooze function” enabled a delay for the diary entry from 5 to 60 minutes if it was inconvenient for the participant to complete the diary entry.

4.7.3 Equipment and materials

A small handheld PDA with diary software was used for each participant. The Dell Axim X51 (with Microsoft Mobile Windows Professional 6.0) was supported by Pocket Interview Version 0.8.4 which was developed at the School of Computing, University of Dundee (Morrison et al., 2009). The behavioural diary collects mobile electronic data which is encrypted using an RC4 cipter (Morrison et al., 2009) to ensure data is secure. These precautions conform to recent NHS Scotland standards for data held on laptops, memory stick and all other mobile devices.

4.7.4 Data collection procedure (EMA Adapted/N-of-1)

A written Standard Operating Procedure (SOP) was developed (see appendix 4.12 for SOP) to ensure that each diary was accurately set up in the same step-wise process, across all 12 electronic diaries. The participants were instructed verbally by the researcher on the diary usage and were given written instructions (see appendix 4.13 for the written instructions). A battery charger was provided to enable the participants to recharge the PDA battery every few days over the course of the month. The researcher contacted the participants by telephone 24 hours after starting the electronic diary, to answer any questions and resolve any issues that may have arisen. At the end of the 1-month period, the researcher met again with the participant to collect the PDA and retrieve the stored data on the device. The electronic diary respondents were interviewed by the researcher to explore their experience of completing the diary; this data are not presented as a part of this thesis.

4.7.5 Measures Repeated Daily

Researchers have to develop diary instruments (Bolger et al., 2003) as there are no standardised instruments available for electronic behavioural diaries. The content of the diary questions were mapped to the constructs of the questionnaires (see appendix 4.14 for diary schedule and screenshot examples of the PDA). The items were informed by the literature and comment from clinicians and prostate cancer patients. The diary structure included 7 questions at standard entry, 12 questions at

end-of-day entry, and 5 questions at incident entry. Most question items were presented on the PDA using a visual analogue scale (VAS) from 0-100 scale. The question items presented on the diary consisted of a 'standard diary entry' (completed 3 times per day), an 'end-of-day entry' (completed once per day, immediately following the third standard entry each day), and an 'incident entry' that could be completed at any time throughout the 1-month period (see table 4.3 for overview and variables).

Table 4.10 Diary structure overview

Enquiry	Variables	Frequency
Standard Entry	Negative and positive affect Coping (positive and negative) Social support (perceived and received) Self-management demand Self-management control Self-management self-efficacy	3 times per day, for a total of 1 month (n=93)
End of Day Entry	Self-management behaviours (urinary, bowel and sexual dysfunction) Additional self-management behaviours Self-management relief of symptoms Self-efficacy Satisfaction social support Most demanding self-management action Medication change Quality of life	Once per day, for a total of 1 month (n=31)
Incident Entry	Description of participants challenging experience Coping (positive and negative) Perceived and received social support Sought social support Positive and negative affect	Event contingent (any time throughout 1-month period)

MOOD: Mood was assessed at the standard entry and the incident entry. Positive and negative affect (Aaron et al., 2005, Affeck et al., 1998, Watson et al., 1988b) was assessed by asking the participants, "*How are you feeling just now? … tired, alert, happy, nervous, frustrated, sad, stressed, energetic, and angry"* using the scale "*not at all/extremely" (0-100)* for each state of affect. This spectrum enabled positive and negative states of affect to be captured.

COPING: Coping was assessed at the standard entry and the incident entry. The coping styles (fighting spirit, helpless/hopeless, anxious preoccupation, fatalistic, avoidance) were based upon the Mental Adjustment to Cancer Scale (Watson and Homewood, 2008, Watson et al., 1988a). Participants were asked to rate each of the following statements taken from the MAC scale: *"I tried to keep a positive attitude"* (positive attitude), "*I felt like giving up"* (helpless/hopeless), *"I felt problems with my*

health prevent me from planning ahead" (anxious preoccupation), *"I felt that nothing I can do will make a difference"* (fatalistic), and *"I tried not to think about it"* (avoidance) using the response scale "*not at all/always" (0-100)* to rate each of the coping styles statements. These items were chosen based on comment and collective agreement from the research steering group.

PERCEIVED SELF-EFFICACY: Self-efficacy was assessed at the standard entry and end-of-day entry. The question items were based on Schwarzer and Jerusalem's (1995) self-efficacy beliefs. At the standard entry, participants were asked to "*Think about the last few hours"* and at the end of day, *"Overall today I feel that",* rating the following statements "*I can always manage to complete self-care activities that are difficult for me"* and "*I am confident in carrying out my self-care activities".* The statements were anchored by "not at all/always" on a 0-100 scale. These items were chosen based on comment and collective agreement from the research steering group.

SOCIAL SUPPORT: This was measured at the standard entry, incident entry and at the end of day entry. Participants were asked about perceived, received and satisfaction with social support. The questionnaire items were based on a multi-dimensional assessment of social support (Schulz and Schwarzer, 2003) and underpinned by the theoretical model (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984, Cohen and Hoberman, 1983). Participants were asked, *"How much support have you had in the last few hours?"* (received social support), rating the following four scales *"financial, emotional, informational and practical",* with all scales anchored by the endpoints, *"none/a lot" on* a 0-100 scale*.* Perceived social support was measured by asking *"Do you have enough available support from people around you?"* and rated by offering the same scales as received social support. During the standard entry, participants were also asked *"Have you sought out support in the last few hours?"* and used a check box to indicate *"yes or no".*

At the incident entry, the question, *"Did you seek out support to help with this experience?"* was asked, using a check box to indicate *"yes or no".* Perceived support was also asked at the incident entry, *"Did you have enough support available from*

people around you?" and *"was that enough support?"* Both items used the response scale *"not at all/always"* (0-100).

SELF-MANAGEMENT DEMAND AND SELF-MANAGEMENT CONTROL: Participants were asked at the standard entry to *"Think about self-care activity in the past few hours*" and rate the following statements *"How demanding has self-care been for you?"* (self-care demand) with the response scale *"not at all/extremely" (0-100)* and *"how much control have you had over your self-care?"* (self-care control) anchored by *"not at all/completely"* (0-100) (Cohen et al., 2000). At the end-of-day entry, *"What was your most demanding self-care task that you had to do today?"* was asked, and, using a keyboard, the participant tapped the letters to form words on the PDA to answer the question.

SELF-MANAGEMENT BEHAVIOURS: The actual self-management behaviours were assessed at the end-of-day entry. The questions addressed 1) the major complaint, 2) actions taken, and 3) effectiveness of the action. The self-management questions were based on previous self-management diary research within cancer (Kim, 2011, Wilson et al., 2010, Dodd, 1997, Nail et al., 1991, Dodd, 1982) and from comment from the steering group/pilot.

To enquire about urinary self-management, "*What types of self-care actions have you used today to help with your waterworks (urine)?"* was asked, and this was answered by selecting the appropriate check box to indicate "*yes"* to various self-care actions, such as "*took medication, found out information, increased fluid intake, used pads, used catheters, …"* For bowel self-management enquiry "*what types of self-care actions have you used today to help with your bowels?"* responding to "*took medication, increased fluid intake, changed diet, used pads, comfort (hot water bottles) …"* Lastly, for sexual function self-management, "*What types of self-care actions have you used today to help with your sexual function?"* was asked, with participants responding "*yes*" to "*took medication, found out information, used a penis pump, shared my feelings …"* To enquire about how effective the self-management actions were in relieving the symptoms (individually for urine, bowel and sexual self-care), the question, *"Generally, did your self-care actions relieve the problem?"* was anchored by "*not at all/completely"* (0-100).

To assess other self-management activities for additional problems or symptoms, "*Did you use any other self-care activities (not already mentioned) to help alleviate your symptoms/problems today?"* was asked, with participants responding by selecting the box to indicate *"yes or no".* If "*yes"* was selected, the request to *"Please describe the problem/symptom for which you carried out your self-care"* and *"Please describe the self-care tasks"* was offered, and the participant responded by tapping letters to form words. To assess about the effectiveness of the action, the question, *"Generally, did your self-care actions relieve this problem?"* was anchored by *"not at all/completely"* (0-100).

HEALTH-RELATED QUALITY OF LIFE/SYMPTOMS: Items were based on the EORTC quality of life instruments for cancer participants that include general and disease-specific HRQoL (Aaronson et al., 1993). Items were asked at the end of day: *"How would you rate your quality of life today?"* anchored by *"very poor/excellent"* on a 0-100 scale, and *"To what extent have you experienced the following symptoms today? (blood in the urine, constipation, diarrhoea, nausea, pain, tiredness, unable to sleep, urgency to pass urine, urinate frequently day, urinate frequently night, vomiting, impotence)"* with each symptom anchored to the end points *"not at all/always"* on a 0-100 scale.

Participants were also asked *"Has there been any change to your treatment/medication today?"*, and answered by selecting the appropriate check box to indicate *"yes or no".* If "*yes",* the option, "*Please describe what the treatment change was"* was offered, with the participant responding by tapping letters on the keyboard to form words.

4.7.6 Sampling framework

The participants were identified from a sampling framework defined by: cancer stage (localised, locally advanced, metastatic), having a partner or not, and self-reports of social support (using the Berlin Social Support Scale [BSSS] at baseline recruitment). Research using the BSSS questionnaire was reviewed (Scholz et al., 2008, Luszczynska et al., 2007a, Boehmer et al., 2007, Schwarzer et al., 2006, Luszczynska et al., 2005) to establish previously reported data on the mean and SD for men with prostate cancer to guide the sampling framework (see appendix 4.15 for overview of the

studies). This sampling framework criteria was important for a number of reasons: 1) this enabled self-management behaviours to be assessed based on the severity of cancer stage, and 2) to explore the influence of social support on self-management behaviours for men affected by prostate cancer (Department of Health Macmillan Cancer Support & NHS Improvement, 2010, Ream et al., 2008, Boberg et al., 2003, Lintz et al., 2003).

The sampling framework used the means and SDs for current study participants (N=11) during the first 2 months of active recruitment. The mean was found to be 3.2 (SD 0.6, [range 2.2 to 4.0]) and participants were recruited using 1 SD (3.8) above to indicate high social support and 1 SD (2.6) below to indicate low social support (see table 4.4 for sampling framework).

Table 4.11 Sampling framework for electronic behavioural diaries

	Partner	No partner
Localised	3.8 ≥ to indicate high social support 2.6 ≤ to indicate low social support	3.8 ≥ to indicate high social support 2.6 ≤ to indicate low social support
Locally advanced	3.8 ≥ to indicate high social support 2.6 ≤ to indicate low social support	3.8 ≥ to indicate high social support 2.6 ≤ to indicate low social support
Metastatic	3.8 ≥ to indicate high social support 2.6 ≤ to indicate low social support	3.8 ≥ to indicate high social support 2.6 ≤ to indicate low social support
Total = 12 individual case studies.		

Participants completed the electronic diary during their 6 months of participation in the study (see table 4.5 for data collection timings). The timings for data collection were informed by clinicians and prostate cancer patients.

Table 4.12 Diary data collection timing

Treatment	Timing of data collection
Radical Prostatectomy (RP)	1 month following RP
External Beam Radiotherapy (EBRT)	1 month following EBRT
Hormone therapy	No timing restrictions (as soon as possible)
Active surveillance (AS)	No timing restrictions (as soon as possible)
Brachytherapy (BT)	1 month following BT

The mean and SD for the BSSS (social support) was re-evaluated at approximately 4 months into active recruitment (N=25). The mean was found to be 3.6 (SD 0.4), calculating the values for the sampling framework as ≤ 3.2 to indicate low social support, and 4.0 to indicate high social support such that, the social support values guiding the sampling framework earlier in the study were considered appropriate.

4.7.7 Statistical analysis (electronic diary)

The electronic behavioural diary data were coded using XML coding and transferred into Microsoft Access (this formed part of the Pocket Interview software). Subsequently, the data were transferred to SPSS version 17.0 to undertake the analysis.

Preliminary analysis (Diary Data)

Prior to the analysis, variables were examined for accuracy of data entry, missing values and the assumptions of the proposed analysis. This was done through traditional exploratory analysis (Tabachnick and Fidell, 2007). Normality distributions of the variables were checked by statistical and graphical methods. Skewness and Kurtosis significance values were checked, the Kolmogorov-Smirnov (K-S) test was performed and a histogram plotted for each variable. Appropriate transformations (Tabachnick and Fidell, 2007) of the variables were performed to reduce skewness, kurtosis, the impact of outliners, and to improve normality, linearity and homoscedasticity.

Autocorrelation and pre-whitening of variables

The data from the single-case studies has the potential to violate the assumption of independence in regression and correlation analysis (Borckardt et al., 2008). Therefore, all variables at standard entry (positive affect, negative affect, positive coping, negative coping, perceived social support, received social support, self-care self-efficacy, self-care demand and self-care control [individually performed for each case study]) were examined for autocorrelation using autocorrelograms produced in SPSS (Tabachnick and Fidell, 2007). If a significant autocorrelation was found, a statistical correction, known as pre-whitening (Cromwell et al., 1994), was used to remove the autocorrelation. By removing the autocorrelation, inferential statistics can be used because the assumption of independence of the data points has been met (Crane et al., 2003, Cromwell et al., 1994). Removing autocorrelation in time series data is essential because without correcting the violated assumption of data independence it may result in inaccurate P Values, and increase the risk of a type 1 or type 2 errors (Borckardt et al., 2008, Tabachnick and Fidell, 2007, Crane et al., 2003, Cromwell et al., 1994).

The pre-whitening procedure has been described by (Tabachnick and Fidell, 2007, Crane et al., 2003) and involves examining the partial plots of autocorrelograms, and then creating a new lagged variable based on the number of lag displayed on the plot. In other words, a plot displaying a first-order autocorrelation would require producing a new time series variable with a lag of 1, using the original variable. The second step in the pre-whitening procedure requires linear regression. The new lagged variable (IV) is used to predict the original variable (non-lagged series) (DV). The unstandardized residuals of the regression analysis become the new pre-whitened variable. The final step in the pre-whitening procedure was to undertake a quality check. This was done by plotting and checking an autocorrelogram of the pre-whitened variable and ensured that the pre-whitening procedure worked in eliminating the presence of autocorrelation in the series.

When variables did not meet the assumptions for analyses, transformations were required (Tabachnick and Fidell, 2007). Transformations of the variables are detailed individually within the presented case studies. Pearson's product moment correlation analysis was performed between all the variables (including unaltered and altered [pre-whitened/transformed] variables). This enabled the researcher to check that the alterations made to the variables did not result in any unexplained relationships (this was performed individually across all of the case studies). Significant relationships were considered at the traditional $P<0.05$ level (Tabachnick and Fidell, 2007).

Moderation

Multiple regression analysis was used to examine moderator effects of figure 4.2. The variables included in the regression were guided by the theoretical model (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984) and having correlations between variables with $P<0.15$ (Tabachnick and Fidell, 2007). The predictor variable and moderator variable were standardised, so that they had a mean of 0 and a standard deviation of 1. Descriptive statistics were undertaken to verify that they were standardised correctly. Standardising the variables makes it easier to plot significant moderation effects and reduces problems of multicollinearity (high correlations) among the variables in the regression equation (Frazier et al., 2004, Aiken and West, 1991). The product term was formed by

multiplying the standardized predictor and standardized moderator variables together.

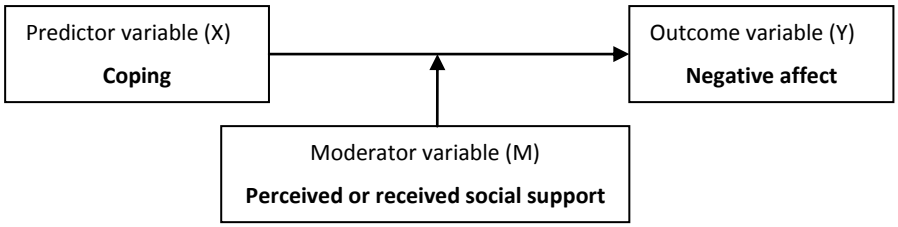


Figure 4.2 Moderation effect

The variables were then entered into hierarchical multiple regression analyses in specified blocks. The first step involved entering the standardised predictor and standardised moderator variable, and lastly, to include the product term in the model (Frazier et al., 2004, Aiken and West, 1991).

Mediation

To test for mediation effects requires performing 3 multiple regression analyses (Frazier et al., 2004, Baron and Kenny, 1986). The first step was to establish that the predictor was related to the outcome. This was achieved by testing the effects of the predictor variable on the outcome variable (testing Path C, as indicated in figure 4.3). If path 'c' was significant, then the first step in mediation was met. The second step was to establish that the predictor and mediator variables were related. This was undertaken by a second regression analysis between the predictor (X) (predictor) on the mediator (M) (outcome). Thus, if path 'a' was significant, then the second condition for mediation holds. The last step was to test the outcome variable (Y) simultaneously on the mediator variable (M) and the predictor variable (X). If the mediator variable (M) was related to outcome variable (Y) then the third step for mediation had been met. Path 'b' is estimated by controlling for the effects of the predictor.

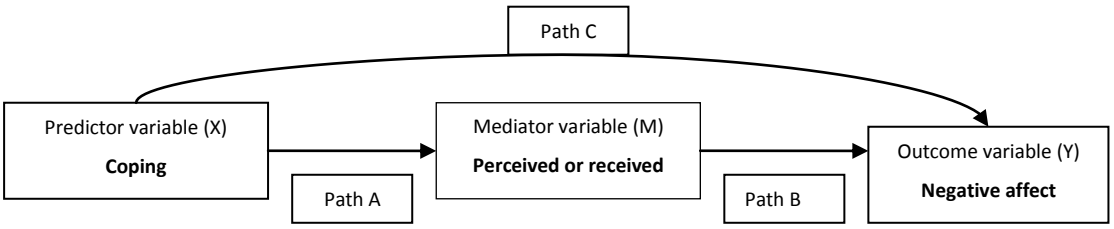


Figure 4.3 Mediation effects

Interpretation involved identifying that the strength of the relationship between the predictor and outcome variables becomes significantly reduced when the mediation variable is added to the model. The Sobel's test (1982) was also performed to establish whether the indirect effect of the independent variable to a dependent variable through a mediator variable was significant. Hayes (2009) identifies that the Sobel's test requires large sample sizes and the assumption that the sampling distribution of the indirect effect is normal. Hayes recommends, in addition to Sobel's tests, that bootstrapping procedures are used because no assumptions about the normality is inferred or limited to large sample sizes. Bootstrapping calculates estimates of the indirect effect at 95% and 99% confidence intervals (CI) for the population of *n* (Preacher and Hayes, 2004). Bootstrapped sample estimates of the indirect effect are interpreted by identifying whether zero is located within the 95% CIs. If zero is not presented within the 95% CI, it can be concluded that a significant mediation effect has occurred. Bootstrapping procedures are based on 5000 random resamples of the data, and, as a result, when repeated, the CIs may differ slightly. The researcher therefore only reported the results of the first bootstrapping procedure. The Sobel's test and the 5000 bootstrapped resamples were calculated using an SPSS script downloaded from Hayes' website http://www.afhayes.com/spss-sas-and-mplus-macros-and-code.html (Preacher and Hayes, 2004).

4.7.8 Managing data collection (electronic diary)

Several issues were important in the process of data collection during the study. It was important that participants in the study did not feel overburdened or confused by what they were asked to do. All instructions and data collection tools were practical, simple and not too long in their completion, to reduce respondent

confusion and burden. The questionnaire pack was piloted to a small group of 6 men and the results identified that the men took between 15-20 minutes to complete the questionnaire pack and, therefore, the length of time was acceptable. Recruitment rates were monitored on a monthly basis by using an Excel graph to plot the actual recruitment figures against the projected recruitment target. This graph was shared with the Ph.D. supervisors to monitor potential problems and to discuss solutions. It became apparent during the recruitment phase of the project that the number of new prostate cancer patients in NHS Tayside was less than the anticipated 230 each year. The researcher attended the clinical sites every week and kept clinical staff informed of the study progress through monthly clinical effectiveness meetings, but the number of new prostate cancer cases was substantially less than expected. To check that the analysis of the prospective longitudinal survey was adequately powered, a power calculation for each multiple regression was performed. Tabachnick and Fidell (2007) recommend a minimum sample size for multiple regression of $N \geq 50 + 8m$ (where m is the number of independent variables); the results of the sample size calculations are reported in chapter 5 (prospective, longitudinal results). The reasons why patients refused to participate in the study, or withdrew from the study, were recorded to assess selection and attrition bias.

4.8 Summary

This chapter has detailed the research questions, the methods chosen and the analysis strategies to address the overall aim and questions set for this study. The purpose of this Ph.D. research was to test the mechanism effect of coping and social support on HRQoL between individuals and within individuals affected by prostate cancer. This Ph.D. also aimed to identify the self-management behaviours of men affected by prostate cancer over time. This study followed a quantitative approach complemented by a prospective, longitudinal survey, and 12 EMA adapted/N-of-1 studies. This approach enabled the theoretical model to be tested between people and within-person change over time to advance understanding, but uniquely positioning the individual patient at the centre of the research. This chapter highlighted that the design and methods chosen in the current study were important for providing insights into, and quantifiable data on, men's social support and self-

management behaviours over the course of their cancer journey. The following chapter discusses the findings from the prospective longitudinal survey.

5.0 Results prospective longitudinal survey

5.1 Abstract

Background

Few prospective longitudinal research designs have been implemented to evaluate changes in coping, social support and self-management in men affected by prostate cancer over time. The implementation of this prospective longitudinal design captured change over time and allowed prediction of HRQoL outcomes which addressed the research questions. Developing an understanding of the mechanism effect that links coping and social support to HRQoL over time can help to identify men who are at high risk of inadequate support and suggest directions for appropriately targeted interventions at an earlier stage in the cancer journey.

Aim

To test the mechanism effects between coping and social support on HRQoL using group level statistics. In addition, the prospective longitudinal survey method was used to assess the self-management behaviours for men affected by prostate cancer over time.

Methods

Participants were asked to complete a battery of questionnaires (QLQ C30 and PR25, Self-Efficacy Scale, MAC Scale, HADS, PSS, Self-Management Log and BSSS) at baseline (approximately 1 month after diagnosis) and at 6 months follow-up (approximately 7 months after diagnosis). Clinical (cancer stage, PSA, Gleason score, treatments, and co-morbidity) and demographic (age, marital status, education, employment, and deprivation) data were also collected. Statistical analysis was performed in SPSS version 17.0 using parametric tests (repeated measures ANOVA, one-way between groups analysis of variance, paired t-tests, bivariate correlations and hierarchical multiple regression) and non-parametric tests (Chi^2 test, Mann-Whitney U and McNemar's test).

Results

Perceived social support (approximately 1 month after diagnosis) was the most important social support construct that predicted global quality of life and depression at six months. Satisfaction with social support (approximately 1 month after diagnosis) had a main effect on depression scores at six months. Social support

constructs did not moderate/mediate the relationship between coping and HRQoL. Men performed a number of self-management behaviours but did not achieve complete symptom control. Secondly, self-care self-efficacy significantly reduced at six months. Global quality of life demonstrated a clinically small relevance and statistically significant decrease at six months, but functional domains of health-related quality of life were mostly unaffected. Disease-specific domains of health-related quality of life were affected in this population and an increase in bowel and sexual dysfunction was identified at six months.

Conclusion

These findings support the main effects social support model, but the propositions of the stress buffering model were not supported in this prospective longitudinal survey. These findings perhaps provide support towards the development of an intervention study to improve quality of life, self-care self-efficacy and improve patients' symptom management. The finding from the individual case studies (chapter 6) may provide useful insight to indicate the content of such an intervention study.

5.2 Introduction

Few prospective longitudinal research designs have been implemented to evaluate changes in coping, social support and the self-management behaviours of men affected by prostate cancer over time. The implementation of this prospective longitudinal design captured change over time and allowed prediction of HRQoL outcomes which addressed the research questions. HRQoL is likely to be affected by the psychological and social factors that unfold over time as men manage, learn from, and adjust to the changes caused by prostate cancer and its associated treatments (Roberts et al., 2006). Little research (Zhou et al., 2010a, Zhou et al., 2010b, Kershaw et al., 2008, Roberts et al., 2006, Visser et al., 2003, Van Andel et al., 2003) has been conducted to identify the relationship between coping and social support on HRQoL at one month after diagnosis and at six months follow-up (Bloch et al., 2007). Understanding the mechanism effect of how coping and social support operate on HRQoL over time can help to identify men who are at high risk of inadequate support and suggest directions for appropriately targeted interventions at an earlier stage in the cancer journey (Roesch et al., 2005).

5.3 Research questions

This prospective longitudinal study addressed the following questions:

1 Approximately 1 month after a prostate cancer diagnosis, what is the relationship between demographic (age, socio-economic status, educational level) and clinical (staging, PSA, Gleason Score, co-morbidity, treatments) variables in men affected by prostate cancer and the following:
a) coping,
b) social support,
c) health-related quality of life,
e) anxiety and depression,
e) self-efficacy,
f) stress,
g) self-management?

2 How does the following change between recruitment 1 month after diagnosis (time 1) and 7 months after diagnosis (time 2):
a) coping,
b) social support,
c) health-related quality of life,
e) anxiety and depression,
e) self-efficacy,
f) stress,
g) self-management?

3 Controlling for baseline (time 1; 1 month after diagnosis) characteristics/variables, does social support (perceived, received and satisfaction level) have a main effect, or does it moderate/mediate the relationship between coping and a) anxiety, b) depression, and c) health-related quality of life, at time 2 (7 months after diagnosis)?

5.4 Methods

Rationale and justification for methods used in this prospective, longitudinal survey study are detailed in chapter 4, section 4.2. Briefly, participants were asked to complete a battery of questionnaires (Prostate Cancer-Specific Self-Management Log, EORTC Quality of life [QLQ C30 and PR25], Self-Efficacy Scale, Mental Adjustment to Cancer Scale, Hospital Anxiety and Depression Scale, Perceived Stress Scale, and the Berlin Social Support Scale) at baseline (approximately 1 month after diagnosis) and at 6 months follow-up (approximately 7 months after diagnosis).

Clinical (cancer stage, PSA, Gleason score, treatments, and co-morbidity) and demographic (age, marital status, education, employment, and deprivation) data were also collected.

5.4.1 Statistical analysis

Data were double-entered in to SPSS version 17.0 and variables were examined for accuracy of data entry, missing values and univariate outliners. Normality of each variable was assessed using statistical (Kolmogorov-Smirnov test and Z-scores for skewness and kurtosis) and graphical methods (histograms with normality plots and Q-Q plots). Scale reliability was assessed using Cronbach's alpha statistic and reviewing *corrected item-domain items* and *Alpha if item deleted.* Statistical analysis was performed using parametric tests (repeated measures ANOVA, one-way between groups analysis of variance, paired t-tests, bivariate correlations and hierarchical multiple regression) and non-parametric tests (Chi^2 test, Mann-Whitney U and McNemar's test). Hierarchical multiple regression analyses were performed to test main, moderation and mediation effects of baseline coping and social support variables on anxiety, depression, and global quality of life at six months. Prior to the regression analysis the evaluations of the assumptions were checked according to guidelines from Tabachnick and Fidell (2007) and Field (2005). To check the assumptions of multiple regression analysis, a series of heuristics are detailed in table 5.1.

Table 5.1 Checklist of assessing assumptions of multiple regression analysis based on guidance suggested by Tabachnick and Fidell (2007) and Field (2005).

Assumption	Check
No perfect multicollinearity	Scan the correlation matrix of all predictor variables (a correlation above .80 suggests multicollinearity). Assess the Collinearity diagnostics (variance inflation factor values of greater than 10 may be of concern) and the tolerance statistic (values below 0.1 indicate serious problems and value below 0.2 are worthy of concern).
Outliners	Review critical Mahalanobis distances. Check the cook's distances (any value greater than 1 indicate a case might be influencing the model).
Non-zero variance	The predictor variables should have some variation in value.
Homoscedasticity, linearity and normality	Review scatterplots (plot *ZRESID against *ZPRED for histogram and normality probability plot)
Independence of errors	The Durbin-Watson test (values of less than 1 and greater than 3 are cause for concern).
Sample size	N=50 + 8m (where m is the number of independent variables)

5.5 Results

5.5.1 Characteristics of the participants

A total number of 109 men newly diagnosed with prostate cancer were invited to take part in the study during April 2012 to March 2011. Seventy-four men consented (67.9 % participation rate) and thirty-four men declined to take part, and one man was excluded because he had already started his radiotherapy (see table 5.2 for an overview of recruitment).

Table 5.2 Recruitment overview

Total number of participants approached	109
Refusing to consent	31
Refused with reasons:	
Patient said "he felt that too much going on after diagnosis and the effects of his hormone therapy"	1
Patient given 2 weeks prognosis to live	1
Patient did not see the benefit for him taking part in the study	1
Too much going on with tests and awaiting results	1
Total consented participants	74 (67.9%)

Distributions of age, cancer stage and cancer treatments between consented and non-consented patients are displayed in table 5.3. Age (non-consented group) was negatively skewed and the Kolmogorov-Smirnoff (K-S) was statistically significant K-S=.263, p=0.000. Various transformations (Tabachnick and Fidell, 2007) were applied to this variable but did not achieve normality. Therefore, the Mann-Whitney U-test was used as the alternative to the parametric t-test for independent samples (Field, 2005). There was no statistical significant difference in age between the consented and non-consented groups U (109) = 1145.05, Z =-0.972, ns. Using Chi^2 test there was no statistical significant difference for cancer stage (Chi^2 = 3.522, df 2, ns) and cancer treatments (Chi^2 = 3.966, df 4, ns) between the consented and non-consented groups.

Table 5.3 Distributions of age, cancer stage and cancer treatments between consented and non-consented patients

	Consented (N=74)	**Non-consented (N=35)**
Age (mean, SD, min-max)	70.05 (8.05) 51-86	71.08 (8.02) 54-85 (*median 74)
Cancer stage:		
Localised	n=32 (43.2%)	n=9 (25.7%)
Locally advanced	n=33 (44.6%)	n=22 (62.9%)
Metastatic	n=9 (12.2%)	n=4 (11.4%)
Treatment:		
Watchful waiting	n=3 (4.1%)	1 (2.9%)
Retropubic radical prostatectomy	n=1 (1.4%)	1 (2.9%)
Laparoscopic radical prostatectomy	n=8 (10.8%)	1 (2.9%)
Radiotherapy	n=6 (8.1%)	7 (20%)
Hormone therapy	n=14 (18.9%)	5 (14.3%)
Active surveillance	n=9 (12.2%)	5 (14.3%)
Hormone therapy and radiotherapy	n=33 (44.6%)	14 (40%)
Chemotherapy and hormone therapy	n=0	1 (2.9%)

*Median value presented for data not normally distributed.

5.5.2 Participant attrition

Participant numbers (n=74) reduced between baseline and 6 months follow-up (n=68) by six participants. Table 5.4 describes the reasons for participant attrition at six months.

Table 5.4 Reasons for participant attrition

Sample attrition at 6 months	
Refused consent	n=5
Deceased	n=1

Table 5.5 displays the distributions of clinical and demographic data for both of the groups. Overall, the response rate was good at six months follow-up (91.9%).

Table 5.5 Distributions of demographic and clinical variables between those who completed the 6 months questionnaire and those who did not complete the 6 months questionnaire

Sample at 6 months n =68		**Participants lost from the study n=6**
Mean age (SD, range)	69.4 (7.97, 51-84)	77.5 (4.51, 73-86)
Education		
High school	n=6	n=1
Further education	n=13	n=2
Higher education	n=17	n=1
Trade qualification	n=27	n=0
No qualifications	n=5	n=2
Employment		
Employed	n=23	n=0
Retired	n=43	n=6
Unemployed	n=2	n=0
Deprivation		
Most deprived 1	n=4	n=0
2	n=5	n=1
3	n=12	n=1
4	n=31	n=2
Least deprived 5	n=16	n=2
Cancer stage		
Localised	n=32	n=0
Locally advanced	n=29	n=4
Metastatic disease	n=7	n=2
Cancer treatment		
Watchful waiting	n=3	n=0
Active surveillance	n=8	n=1
Retropubic radical prostatectomy	n=1	n=0
Laparoscopic radical prostatectomy	n=8	n=0
Radiotherapy	n=6	n=0
Neoadjuvant hormone therapy + radiotherapy	n=32	n=1
Hormone therapy	n=10	n=4
Gleason Score		
6	n=30	n=1
7	n=20	n=2
8	n=9	n=2
9	n=9	n=1
Prostate Specific Antigen (median, min-max)	*14.55 (4.8-300.0)	* 17.2 (12.1-134.9)
Co-morbidity		
No pre-existing co-morbidity	n=22	n=1
1 co-morbidity	n=8	n=3
2 co-morbidities	n=18	n=0
3 co-morbidities	n=10	n=1
4 co-morbidities	n=5	n=0
5 co-morbidities	n=5	n=1

*Median value presented for data not normally distributed.

The frequencies of existing health problems are displayed in figure 5.1. The most prevalent co-morbidities were hypertension (45.9%) and arthritis (21.6%); this data are similar to those reported by Klabunde et al. (2005).

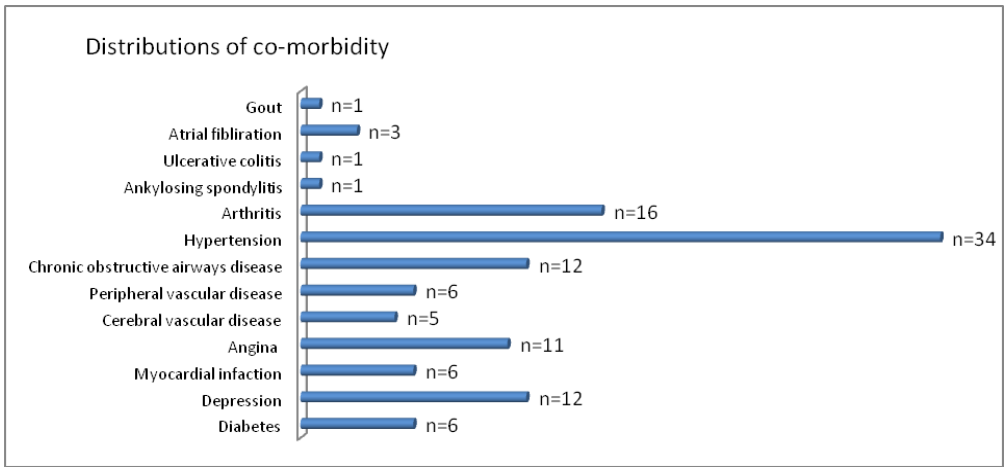


Figure 5.1 Distributions of co-morbidity (N=74)

5.5.3 Completion rates of HADS, MAC Scale, EORTC C30 and PR25, Self-management log, Self-Efficacy Scale, PSS and BSSS.

Seventy-two participants completed the questionnaires at baseline and sixty-eight participants completed the questionnaires at six months follow-up. Two participants did not complete the survey at baseline because one participant withdrew from the study after consent, and the other did not return his survey. Four participants did not return their 6 months follow-up questionnaire.

HADS

There were no missing data at baseline but there was one single missing item on the depression scale at 6 month follow-up. The missing value was replaced with the participant's mean depression score (Tabachnick and Fidell, 2007).

MAC SCALE

At baseline there were seven missing items (two missing items on the Helpless/Hopeless scale, three missing items on the Pre-anxious Occupation scale and two missing items on the Fighting Spirit scale) for three participants' data. There were two missing items at 6 months follow-up (one item on Fighting Spirit scale and one item on the Fatalistic scale) for two participants' data. The missing items for each subscale were replaced with the individual participant's mean score for each subscale, for the five participants' data (Tabachnick and Fidell, 2007).

EORTC C30

At baseline the global quality of life scale items were missing from one participant's data and his data were excluded from any further analysis that utilised this variable. There were no further missing items at baseline.

At six months, one participant did not complete the first full page of the C30; as a result, the functional scales (physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning) and single symptom items (vomiting, nausea, appetite loss, fatigue, breathlessness, pain) are missing. This participant was excluded from further analysis using these subscales. There were no further missing data at 6 months follow-up.

EORTC PR25

At baseline one participant did not complete the Sexual Activity scale and seven participants did not complete the Bowel Function scale. Participants (n=8) who omitted more than 5% of items were excluded from the analysis (Tabachnick and Fidell, 2007). There were no further missing data at baseline.

At six months one participant did not complete the Urinary Function scale and was excluded in any further analysis using this variable. One single item was missing from the Urinary Function scale and was replaced with the participant's mean score for his urinary function scale (Tabachnick and Fidell, 2007). Eight participants did not complete the Bowel Function scale and one participant did not complete the Treatment Related Symptoms scale and were excluded from any further analysis that utilised these variables. One single item was missing from the sexual activity scale and this value was not replaced with the participant's mean score as there were only two items in this scale.

SELF-MANAGEMENT SELF-EFFICACY SCALE

There were no missing data at baseline. Two single items were missing at six month follow-up and the missing values were replaced with the participant's mean score (Tabachnick and Fidell, 2007).

SELF-MANAGEMENT LOG

One participant did not complete the self-management log at baseline. There were no missing data at 6 month follow-up.

PERCEIVED STRESS SCALE

There were no missing data at baseline or at 6 months follow-up.

BERLIN SOCIAL SUPPORT SCALE

At baseline two participants did not complete the Received Social Support scale and the Satisfaction with Social Support scale and were excluded from any further analysis that utilised this variable. There was no further missing data at baseline.

At six months follow-up one participant did not complete the Perceived Social Support scale and was excluded from any further analysis that utilised this variable. Two participants had a single item missing on the Received Support scale and these values were replaced with the participants' individual mean score for this variable. There were no other missing data.

5.5.4 Data screening

Normality of distributions of all the variables at baseline and six months were assessed using the Kolmogorov-Smirnov (K-S) test and Z-scores, histograms with normality plots and Q-Q plots. To assess the significance of the z-score, values greater than 1.96 was significant at $p<0.05$, above 2.58 was significant at $p<0.01$ and above 3.29 was significant at $p<0.001$ (Field, 2005). Variables that were non-normal in distribution were transformed (Tabachnick and Fidell, 2007) to reduce skewness and kurtosis, reduce the impact of univariate outliners, and to improve normality, linearity and homoscedasticity. Variables displaying skewness and kurtosis were transformed using a square root transformation (PSA, received social support at baseline, global quality of life at baseline at six months, fatigue at baseline and at six months, urinary symptoms at baseline and at six months, and treatment symptoms at baseline and at six months) and a log transformation (depression at baseline and

at six months). Normality of distribution was re-assessed after the transformation had been applied to variables to ensure normality of distribution had been achieved.

PSA was positively skewed and positively kurtotic and the K-S (68) =.289, p=.000, and displayed one univariate outliner. A square root transformation was successfully applied and achieved normality of distribution. Depression scores at baseline and at six months were significantly positively skewed and successfully transformed using a log transformation (Field, 2005). Anxiety scores at baseline and at six months were significantly positively skewed and a square root transformation was applied and achieved normality in distribution for these variables. Global quality of life values at baseline and at six months were significantly negatively skewed and positively kurtotic and a square root transformation was applied to both variables and achieved normality in distribution. Received social support at baseline was significantly positively skewed and kurtotic and the K-S (65) =0.263, P=0.000. A square root transformation was applied to the following variables: baseline received social support, treatment symptoms, urinary symptoms, and fatigue, and the transformations achieved normality for these variables.

5.5.5 Reliability analysis

Reliability of the subscales at baseline and six months were assessed using the Cronbach's alpha statistic. Acceptable Cronbach's values are recommended at ≥0.70 and having corrected item-total correlations above 0.3 (Tabachnick and Fidell, 2007, Field, 2005). All subscale scales met the recommended criteria except for the EORTC C30 cognitive function at baseline (Cronbach's alpha 0.55) and at six months (Cronbach's alpha 0.58). It is acknowledged that item numbers in a scale will affect the value of the Cronbach's alpha (Field, 2005). The cognitive function subscale had only 2 items but had item correlations above 0.3, therefore the reliability of this subscale was considered to be satisfactory (Field, 2005). The EORTC PR25 bowel symptoms scale and the treatment symptoms scale at baseline and at six months did not meet the recommended Cronbach's alpha level. At baseline, the bowel symptoms scale (0.51) had two items with correlations less than 0.3 and one item with correlations less than 0.3 at six months. The Cronbach's alpha value would not have improved if the items with correlations <0.3 were deleted; therefore the items

were not removed from the subscale. Treatment symptoms at baseline (0.41) and treatment symptoms at six months (0.59) had item correlations less than the recommended >0.3 for four items at baseline and two items at six months. The reliability of the scale did not improve after assessing the *Alpha if Item deleted* for the items with correlations less than 0.3, therefore these items were not removed from the scales.

5.5.6 Baseline associations with demographic and clinical variables with the questionnaire survey

To address the first research question a one-way between groups' analysis of variance was performed to investigate differences in categorical variables, namely: demographic: socio-economic and education; and clinical variables: cancer staging, treatments; and Gleason score with the following dependent continuous variables: anxiety $_{(\text{square root})}$, depression $_{(\log)}$, and global quality of life $_{(\text{square root})}$. No statistically significant differences were found between clinical and demographic variables with anxiety $_{\text{square root}}$, depression $_{\log}$, and global quality of life $_{\text{square root}}$.

A one way between groups' analysis of variance was used to assess differences in demographic (socio-economic and education) and clinical variables (cancer staging, treatments, and Gleason score) with self-management self-efficacy, coping, social support (perceived, received and satisfaction) and perceived stress. No statistical difference was found between clinical and demographic variables with the following: self-management self-efficacy, perceived social support, received social support $_{\text{square root}}$, satisfaction with social support and perceived stress. The results of the one-way between groups' analysis of variance are detailed in appendix 5.1

There was a statistically significant difference between negative coping scores for the four SIMD (socio-economic) groups $F(4, 63) = 3.52$, $p=0.012$. The mean scores and SD's across the SIMD groups are as follows: SIMD 1 most deprived, 31.75 (SD 10.34); SIMD 2, 38.2 (SD 5.76); SIMD 3, 26.67 (SD 3.89); SIMD 4 least deprived, 28.88 (SD 6.58). The effect size was calculated using eta squared and was 0.18, indicating a large effect size (Cohen 1988). Post-hoc comparisons using the Tukey HSD test indicated that the mean for SIMD groups 3 and 4 (least deprived) were significantly different from SIMD groups 1 and 2 (most deprived). Therefore, men in lower socio-

economic groups are more likely to report higher negative coping following a prostate cancer diagnosis. No significant differences were found between negative coping and the following variables: level of education, cancer stage, treatment and Gleason score.

A one-way between groups' analysis of variance was conducted to explore the impact of levels of education on the scores of positive coping. There was a statistically significant difference in positive coping scores and level of education F (2, 65) =3.78, p=0.02. The mean score for the 3 education groups are as follows: high school education 54, 24 (SD 6.69), further education (i.e. college) 51, 69 (SD 5.97), higher education (i.e. university) 49.59 (SD 5.59). The effect size calculated using eta squared was 0.10, indicating a large effect size (Cohen 1988). Post-hoc comparisons using the Turkey HSD test indicated that the mean score for higher education (i.e. university) was significantly different from high school education. Men with a lower level of education are more likely to have higher positive coping than those individuals with a higher level education. No significant differences were found between positive coping scores and the following variables: socio-economic status, cancer stage, treatment and Gleason score.

Chi² tests were used to explore the relationship between two categorical variables. Chi² tests demonstrated no statistical significant differences between the self-management of urinary, bowel and sexual dysfunction with the following variables: socio-economic, educational level, cancer stage, treatments, and Gleason score.

A Pearson's product-moment correlation were performed with continuous demographic (age) and clinical variables (PSA and number of co-morbidities) with the following continuous baseline survey variables: positive coping, negative coping, anxiety $_{\text{square root}}$, depression $_{\text{log}}$, self-management self-efficacy, perceived stress, perceived social support, received social support $_{\text{square root}}$, satisfaction with social support, EORTC C30 subscales and the EORTC PR25 subscales. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. The results of the Pearson's product-moment correlation coefficients are details in table 5.6.

Table 5.6 Pearson's' product-moment correlations coefficients between clinical and demographic variables at baseline and the questionnaire survey variables at baseline

	Age	PSA $_{\text{Square root}}$	Number of co-morbidities
MAC Scale, positive coping	0.000	-0.176	-0.267**
MAC Scale, negative coping	-0.115	-0.072	0.091
Perceived stress	-0.183*	-0.221*	0.194*
Self-management self-efficacy	-0.086	0.181*	0.138
Received social support $_{\text{Square root}}$	0.178*	0.030	0.307**
Perceived social support	-0.182*	-0.221*	-0.152
Satisfaction social support	-0.026	0.086	0.002
HADS, Anxiety $S_{\text{quare root}}$	-0.114	-0.131	0.106
HADS, Depression $_{\text{Log}}$	0.362***	-0.120	0.411***
EORTC C30, Physical function	-0.504***	-0.078	-0.467***
EORTC C30, Role function	-0.401***	0.038	-0.278**
EORTC C30, Emotional function	0.007	0.049	-0.096
EORTC C30, Cognitive function	-0.290**	0.070	-0.193
EORTC C30, Social function	-0.166	0.070	-0.234*
EORTC C30, Global quality of life $_{\text{Square root}}$	-0.390***	-0.081	-0.459***
EORTC C30, Nausea and vomiting	-0.335***	-0.165	-0.087
EORTC C30, Pain	0.162	0.189*	0.225
EORTC C30, Dyspnoea	0.396***	0.110	0.342**
EORTC C30, Insomnia	0.051	-0.196*	0.145
EORTC C30, Appetite loss	0.014	0.027	-0.014
EORTC C30, Constipation	0.147	0.226*	0.059
EORTC C30, Diarrhoea	0.145	0.278*	0.109
EORTC C30, Fatigue $_{\text{Square root}}$	0.290**	0.160	0.354**
EORTC C30, Financial difficulties	-0.068	-0.143	0.031
EORTC PR25, Urinary symptoms $_{\text{Square root}}$	0.232*	-0.038	0.149
EORTC PR25, Bowel symptoms	0.071	0.013	-0.107
EORTC PR25, Treatment symptoms	-0.076	0.212*	-0.058
EORTC PR25, Incontinence aid	-0.153	-0.227	0.000
EORTC PR25, Sexual activity	-0.329***	-0.190*	0.196
EORTC PR25, Sexual function	0.162	0.150	0.223

*significant level p<0.15, ** significant level p<0.05, ***significant level p<0.01 (n=68)

Age had a number of statistically significant associations at the p<0.01 level with the following variables: depression $_{\text{log}}$ (r= 0.362), physical function (r=-0.504), role function (r=-0.401), global quality of life $_{\text{square root}}$ (r=-0.390), nausea and vomiting (r=-0.335), dyspnoea (r=0.396), and sexual activity (r=-0.329). The significant associations with age are in keeping with existing research (Gacci et al., 2009, White et al., 2008, Jayadevappa et al., 2005). PSA $_{\text{square root}}$ did not have any statistically significant associations on global quality of life, anxiety and depression, and is similar to data published by (Lintz et al., 2003). The number of co-morbidities had a number of moderate, positive correlations with depression $_{\text{log}}$ (r=0.411, p<0.01), dyspnoea (r=0.342, p<0.05) and fatigue $_{\text{square root}}$ (r=0.354, p<0.05. Co-morbidity had negative

associations with physical function (r=-0.467, p<0.01), role function (r=-0.278, p<0.05) and global quality of life $_{\text{square root}}$ (r=-0.459, p<0.01).

5.5.7 Assessing change over time from baseline to six months for the questionnaire survey variables

To answer the second research question, paired sampled t-tests were performed to explore changes in the mean scores of the questionnaire survey variables at time 1 (baseline) and time 2 (six months follow-up).

HADS

The results of the paired sampled t-tests are displayed in table 5.7. No statistical significant difference was found in the mean scores for anxiety $_{\text{square root}}$, depression (t=0.480, ns) and depression $_{\text{log}}$, (t=-1.097, ns) between baseline and six months.

Table 5.7 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for HADS

Anxiety	**N**	**Cronbach's α**	**Mean (SD)**	**t value and significance**
Baseline	68	0.82	4.62 (3.34)	t(67)=0.480, ns
Six months	68	0.85	4.53 (3.67)	
Depression				
Baseline	68	0.78	2.88 (2.76)	t(67)=-1.097, ns
Six months	68	0.74	3.32 (2.93)	

The "cut-off" scores recommended by Zigmond and Snaith (1983) were used to calculate non-cases (0-7), possible cases (8-10) and probable cases (11+) of anxiety and depression. The distribution of participants categorised with these cut-off scores are displayed in table 5.8.

Table 5.8 Percentage distribution of participants defined by HADS cut-off scores at each time point

Anxiety	**Non-cases (0-7)**	**Possible cases (8-10)**	**Probable cases (11 +)**
Baseline	n=57 (83.8%)	n=8 (11.8%)	n=3 (4.4%)
Six months	n=53 (77.9%)	n=9 (13.2%)	n=6 (8.8%)
Depression			
Baseline	n=68 (92.6%)	n=4 (5.9%)	n=1 (1.5%)
Six months	n=61 (89.7%)	n=5 (7.4%)	n=2 (2.9%)

MAC Scale

The results of the paired sampled t-tests are displayed in table 5.9. No statistically significant difference was found in the mean scores for positive coping (t=0.796, ns) and negative coping (t=0.802 ns) between baseline and six months.

Table 5.9 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for MAC Scale

Positive coping	**N**	**Cronbach's α**	**Mean (SD)**	**t value and significance**
Baseline	68	0.83	52.15 (7.53)	t(67)=0.796, ns
Six months	68	0.83	51.99 (7.48)	
Negative coping				
Baseline	68	0.77	29.21 (6.53)	t(67)=0.802, ns
Six months	68	0.84	25.56 (7.35)	

Self-management self-efficacy

The results of the paired sampled t-tests are displayed in table 5.10. A statistically significant difference was found between the mean scores for self-management self-efficacy (t=3.17, p=0.002) at baseline and six months. The mean self-management self-efficacy score at baseline worsened from 3.8 (SD.37) to 3.49 (SD.85) at six months, see figure 5.2.

Table 5.10 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for self-management self-efficacy scale

Self-management self-efficacy	**N**	**Cronbach's α**	**Mean (SD)**	**t value and significance**
Baseline	68	0.89	3.80 (0.37)	t(67)=3.17, p=0.002
Six months	68	0.96	3.49 (0.85)	

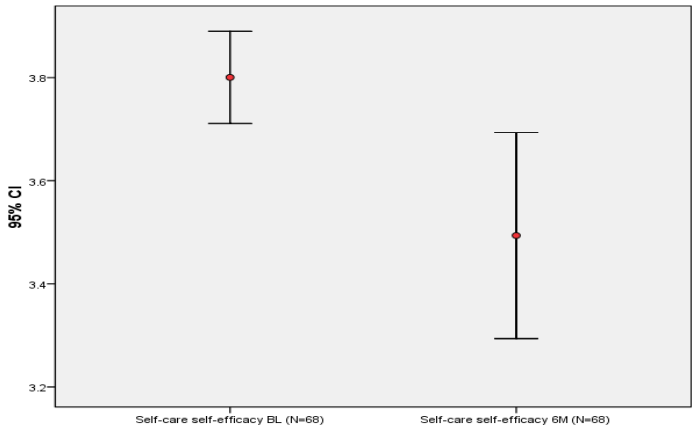


Figure 5.2 Mean self-management self-efficacy scores and error bars at baseline and at six months follow-up

Perceived Stress Scale

No statistically significant difference was found in the mean scores for perceived stress (t=-1.85, ns) at baseline and six months (see table 5.11).

Table 5.11 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for perceived stress scale

Perceived stress	N	Cronbach's α	Mean (SD)	t value and significance
Baseline	68	0.89	10.29 (5.81)	t(67)=-1.85, ns
Six months	68	0.96	11.74 (7.50)	

Social support

Paired sampled t-tests identified no statistically significant difference in the mean scores for perceived social support (t=-1.42, ns) and mean score for satisfaction level of social support (t=1.00, ns) (see table 5.12). A statistical significant difference was found in the mean scores for received social support (t=-2.19, p=0.031) at baseline and six months. A trend of increased received social support is displayed in figure 5.3.

Table 5.12 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for perceived stress scale

Berlin social support scale	N	Cronbach's α	Mean (SD)	t value and significance
Perceived social support				
Baseline	67	0.87	2.61 (1.21)	t(66)=-1.42, ns
Six months	67	0.88	2.78 (1.21)	
Received social support				
Baseline	66	0.86	1.68 (.81)	t(65)=-2.19, p=0.031
Six months	66	0.87	1.97 (.99)	
Satisfaction of social support				
Baseline	64	Single item	3.89 (.40)	t(63)=1.00, ns
Six months	64	Single item	3.83 (.49)	

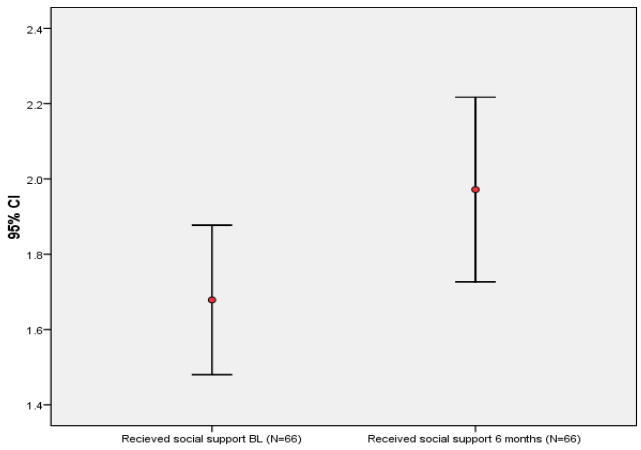


Figure 5.3 Mean received social support scores and error bars at baseline and at six months follow-up

The distributions of participants' usage of additional cancer support services, namely: 1) prostate cancer support groups; 2) additional support services (for example online prostate cancer forums); and 3) Maggie's Cancer Care Centre, are displayed in table 5.13. At baseline no men engaged with prostate cancer support groups and at six months follow-up, four men (5.9%) reported attending a prostate cancer support group every several months. No men reported using additional cancer support services at baseline or at six months follow-up.

At baseline, seven men (10.3%) reported attending Maggie's Cancer Care Centre, four men reported using the centre on a daily basis and three men attended the centre every several months. The number of men attending Maggie's increased from 10.3% at baseline to 16.2% at six months (see table 5.13 for the frequencies of attendance). The main themes of support provision received at Maggie's included: informational support, Government benefit informational support, prostate cancer peer support and an individual counselling session. At six months follow-up, 83.8% of the participants did not use Maggie's cancer care centre for additional help or support.

Table 5.13 Distributions of the frequencies of participants usage of cancer services (n=68)

	User of prostate cancer support group	**Frequency of attendance of support group**	
Baseline Yes No	 n=0 n=68	 N/A	
Six months Yes No	 n=4 (5.9%) n=64 (95.1%)	 Every several months n=4 N/A	
	Additional cancer support (i.e. online prostate cancer forums)	**Frequency of usage of additional cancer support**	
Baseline Yes No	 n=0 n=68	 N/A n=68	
Six months Yes No	 n=0 n=68	 N/A n=68	
	User of Maggie's Cancer Care Centre	**Frequency of attendance of Maggie's Cancer Care Centre**	**Type of Support used at Maggie's Cancer Care Centre**
Baseline Yes No	 n=7 (10.3%) n=61 (89.7%)	 Daily n=4 Every several months n=3 N/A =n=61	 Government benefit support information n=1 Informational support n=6
Six Months Yes No	 n=11(16.2%) n=57 (83.8%)	 Several times monthly n=3 Monthly n=1 Every several months n=6 Yearly n=1 N/A n=57	 Government benefit support information n=3 Individual psychology session n=1 Prostate cancer networking group n=1 Informational support n=6

EORTC C30 Health-related quality of life

The results of the paired sampled t-tests demonstrated no statistical significant difference for role function, cognitive function, emotional function and social function at baseline and six months (see table 5.14). Global quality of life (t=2.35, p=0.021) and physical function (t=2.82, p=0.006) significantly reduced over time from baseline to six months (see table 5.14).

Table 5.14 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for the EORTC C30 subscales

EORTC C30	n	Cronbach's α	Mean (SD)	t value and significance
Global quality of life				
Baseline	67	0.84	78.48 (14.29)	t(66)=2.35, p=0.021
Six months	67	0.85	73.28 (16.78)	
Physical function				
Baseline	67	0.72	87.55 (15.91)	t(66)=2.82, p=0.006
Six months	67	0.81	82.59 (16.89)	
Role function				
Baseline	67	0.83	87.06 (22.06)	t(66)=1.72, ns
Six months	67	0.91	82.09 (27.11)	
Cognitive function				
Baseline	68	0.55	83.82 (17.74)	t(68)=-1.19, ns
Six months	68	0.58	81.37 (20.87)	
Emotional function				
Baseline	68	0.84	79.90 (19.44)	t(67)=-0.20, ns
Six months	68	0.88	79.53 (20.94)	
Social function				
Baseline	68	0.87	86.76 (21.66)	t(67)=0.21, ns
Six months	68	0.75	86.03 (19.66)	

The results of the paired sampled t-tests demonstrated no statistical significant difference for dyspnoea, pain, diarrhoea, and financial difficulties (see table 5.15). A statistically significant difference was found for increased appetite loss (t=-2.41, p=0.019), fatigue (t=-2.431, p=0.018) and constipation (t=-2.19, p=0.032) from baseline to six months.

Table 5.15 Results of the paired samples t-tests for the EORTC C30 single item scales

EORTC Individual items	N	Mean (SD)	t value and significance
Dyspnoea			
Baseline	67	21.89 (30.56)	t(66)=0.000, ns
Six months		21.89 (28.16)	
Pain			
Baseline	67	9.45 (15.41)	t(66)=1.405, ns
Six months		12.44 (17.49)	
Appetite loss			
Baseline	67	2.49 (8.84)	t(66)=-2.41, p=0.019
Six months		6.97 (14.83)	
Constipation			
Baseline	68	9.80 (20.81)	t(67)=-2.19, p=0.032
Six months		14.71 (22.59)	
Diarrhoea			
Baseline	68	9.31 (22.19)	t(67)=-0.646, ns
Six months		11.27 (16.89)	
Fatigue			
Baseline	67	19.06 (2.52)	t(66)=-2.431, p=0.018
Six months		21.38 (2.61)	

Financial difficulties			
Baseline	68	8.33 (21.85)	t(67)=0.000, ns
Six months		8.33 (18.55)	

EORTC PR25 Disease-specific health-related quality of life

The results of the paired sampled t-tests demonstrated a statistically significant increase in bowel symptoms (t=-2.97, p=0.004) and treatment related symptoms (t=-5.04, p=0.000) at six months, see table 5.16. No statistically significant change was identified for urinary symptoms. Sexual activity statistically reduced at six months (t=-1.74, p=0.045). At baseline, twenty-eight men were sexually active (41.2%) and the number of men sexually active at six months reduced to fifteen (22.1%).

Table 5.16 Results of the paired samples t-tests and reliability analysis using Cronbach's alpha statistic for the EORTC PR25 subscales

EORTC PR25	**N**	**Cronbach's α**	**Mean (SD)**	**t value and significance**
Urinary symptoms				
Baseline	67	0.85	17.06 (2.08)	t(66)=-0.722, ns
Six months	67	0.85	18.47 (2.26)	
Bowel symptoms				
Baseline	55	0.51	5.45 (9.10)	t(54)=-2.97, p=0.004
Six months	55	0.57	11.06 (14.62)	
Treatment symptoms				
Baseline	67	0.41	9.37 (10.11)	t(66)=-5.04, p=0.000
Six months	67	0.59	17.16 (15.62)	
Sexual activity				
Baseline	64	0.88	45.12 (5.64)	t(63)=-1.74, p=0.045
Six months	64	0.79	39.11 (4.89)	
Sexual function				
Baseline	15	0.57	31.11 (21.24)	t(14)=3.70, p=0.002
Six months	15	0.79	56.11 (29.79)	

Sexual functioning significantly improved from baseline to six months for men (n=15) who were sexually active (t=3.70, p=0.002) (see figure 5.6).

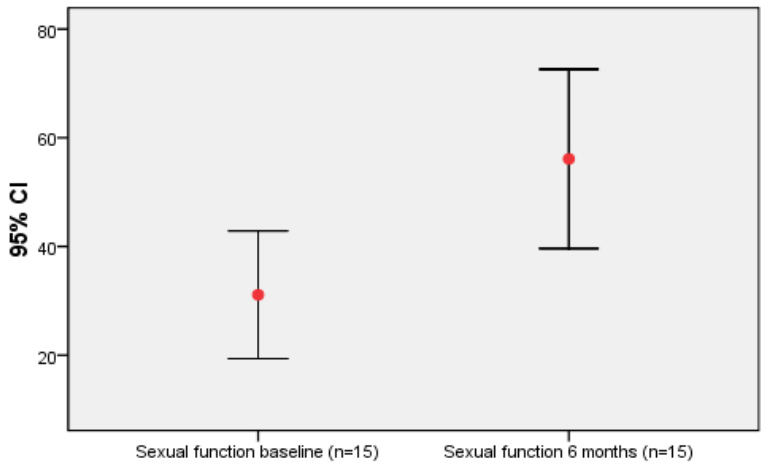


Figure 5.4 Mean sexual function scores and error bars at baseline and at six months follow-up

Self-management log

The McNemar's test was used to assess statistical differences between two related groups for categorical data (Petrie and Sabin, 2005) measured at two time points (baseline and six months). The McNemar's test compared the frequency of men who performed self-management and those individuals who did not perform self-management, at baseline and at six months. Separate McNemar's tests were performed to assess differences in the frequncies of urinary, bowel and sexual dysfunction self-management at baseline and six months.

Urinary self-management

Using the McNemar's test, a significant difference was found in the number of men (n=68, across the whole sample) performing urinary self-management at baseline and at six months p=0.024. The percentage of men performing urinary self-management decreased from 51.5% at baseline to 38.6% of men at six months. The self-management behaviours for urinary symptoms are displayed for localised prostate cancer in figure 5.7. Men diganosied with localised prostate cancer performed a number of self-management behaviours to alleviate urinary symptoms at baseline and at six months.

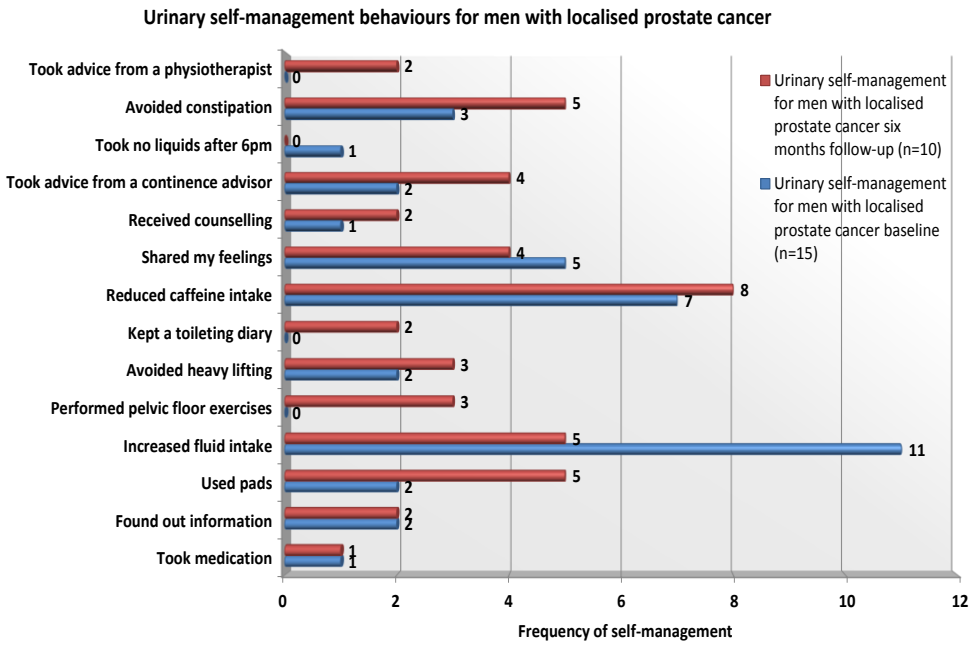


Figure 5.5 Frequency distributions of urinary self-managment for men with localised prostate cancer

The effectiveness of self-management behaviours for symptom relief was measured using self-reports on a 1-5 scale (1 = no relief, 2 = got a little relief, 3 = got some relief, 4 = got quite a bit of relief, 5 = completly relieved). A total maximum mean score of 5.0 for self-management relief would indicate complete symptom relief. The mean score for urinary self-management symptom relief was 2.62 (SD 1.15) at baseline, and 3.64 (SD 1.26) at six months for men with localised prostate cancer.

The urinary self-management behaviours performed by men with locally advanced prostate cancer are displayed in figure 5.8. The mean score for urinary management relief for participatns with locally advanced prostate cancer was 3.12 (SD 1.30) at baseline and 2.45 (SD .85) at six months.

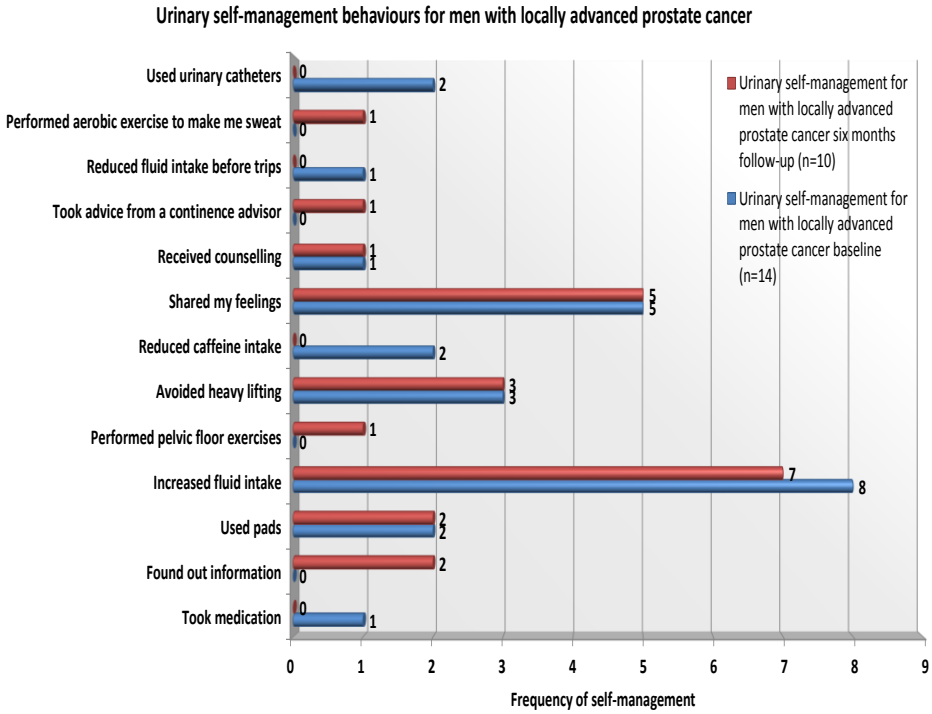


Figure 5.6 Frequency distribtions of urinary self-management behaviours for men with locally advanced prostate cancer

The self-management behaviours to allaivate urinary symptoms for men with metastatic prostate cancer are displayed in figure 5.9. The mean score for urinary self-management symptom relief was 3.10 (SD .82) at baseline and 3.58 (SD .52) at six months. Noticably, there were not as many self-management behaviours performed by men with metastatic cancer compared to men with localised or locally advanced cancer.

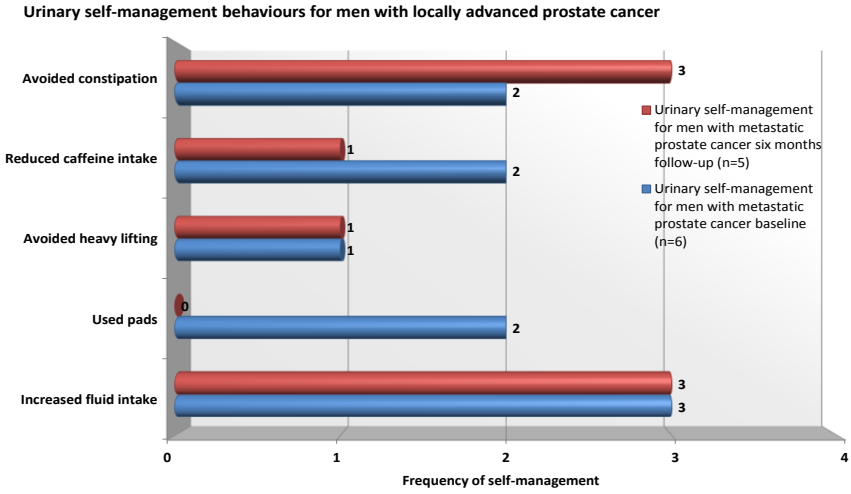


Figure 5.6 Frequency distributions of urinary self-management behaviours for men with metastatic prostate cancer

Descriptively, men with localised and locally advanced prostate cancer performed a greater variety of self-management behaviours for urinary problems compared to participants with metastatic prostate cancer. Overall, men (localised, locally advanced and metastatic cancer) who performed urinary self-management at baseline and at six months did not achieve complete symptom relief through self-management behaviours.

Bowel self-management

The percentage of men (based on all participants [n=68] in the study) performing bowel self-management significantly increased from 14.9% at baseline to 30.9% at six months (McNemar's test p=0.002). The self-management behaviours for bowel symptoms are displayed for localised prostate cancer in figure 5.9. The mean score for bowel symptom relief from self-management actions was 3.5 (SD 0.71) at baseline and 3.26 (SD 0.80) at six months, but overall, the number of men with localised prostate cancer performing self-management for bowel problems at baseline (n=2) and six months (n=4) were small compared to the number of men performing urinary self-management.

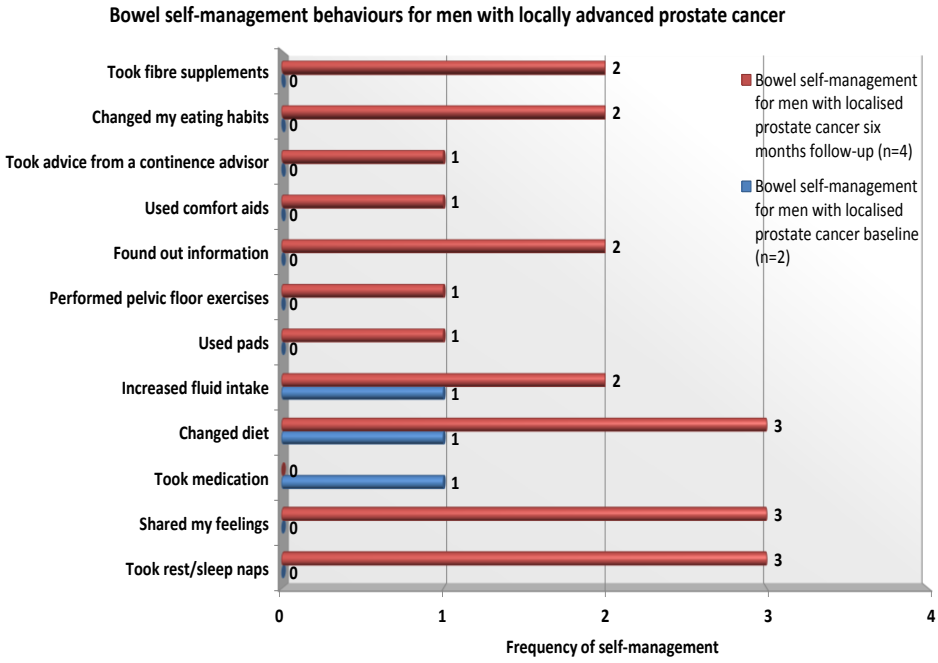


Figure 5.7 Distributions of bowel self-management behaviours for men with localised prostate cancer

The self-management behaviours for bowel symptoms are displayed in figure 5.10 for men with locally advanced prostate cancer. The mean score for bowel symptom relief from self-management was 2.72 (SD 0.83) at baseline and 3.33 (SD 0.58) at six months. The number of men with locally advanced prostate who performed bowel self-management increased from five men at baseline to eleven men at six months.

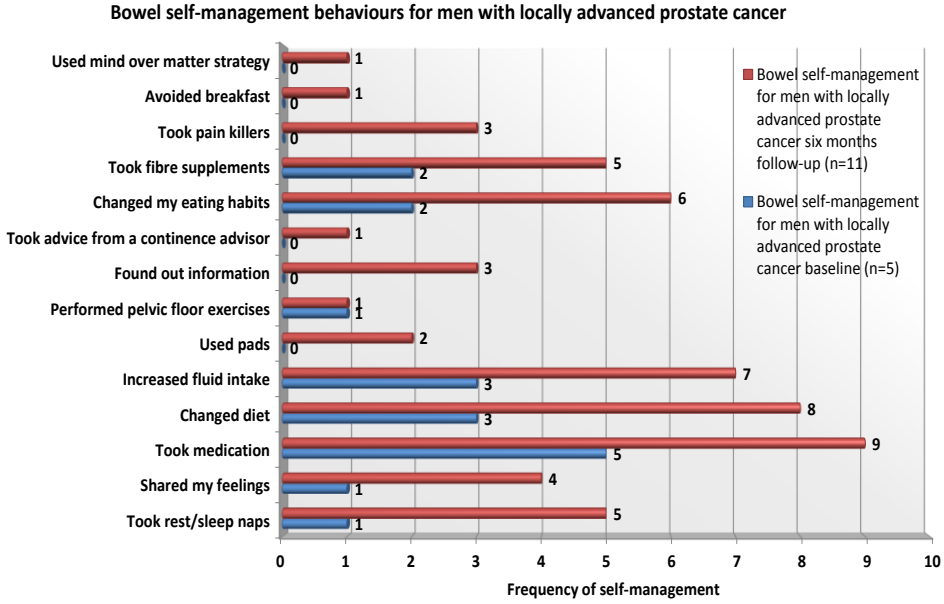


Figure 5.8 Distributions of bowel self-management behaviours for men with locally advanced prostate cancer

The bowel self-management behaviours for men affected by metastatic cancer are displayed in figure 5.11. The mean score for bowel symptom relief from self-management was 3.82 (SD 0.70) at baseline and 3.0 (SD 0.79) at six months. The number of men performing self-management for bowel problems increased from baseline (n=2) and six months (n=6).

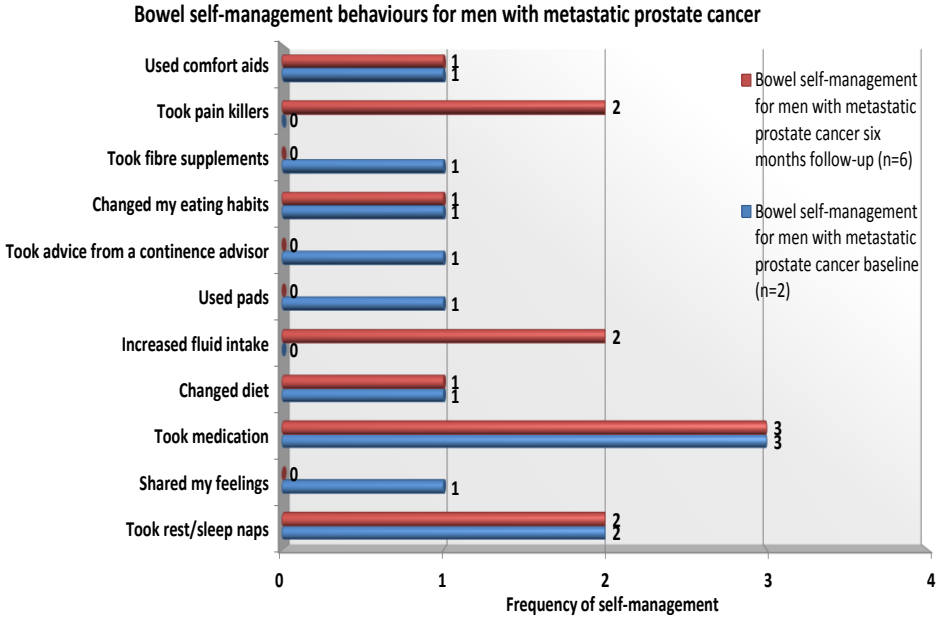


Figure 5.9 Distributions of bowel self-management behaviours for men with metastatic prostate cancer

In summary, bowel self-management was most frequently reported by men with locally advanced prostate cancer. Men (localised, locally advanced and metastatic cancer) who performed bowel self-management at baseline and at six months did not achieve complete relief through their self-management behaviours.

Sexual function self-management

The percentage of men (based on all participants [n=68] in the study) reporting self-management for sexual dysfunction increased from 45.6% at baseline to 52.9% at six months, however was not statistically significant (McNemar's test, ns). The frequencies of sexual function self-management behaviours for men with localised disease are displayed in figure 5.12. Fourteen men (43.7%) with localised cancer performed sexual function at baseline and sixteen (50%) men performed sexual function self-management at six months. The mean score for sexual function relief from self-management was 2.57 (SD 1.46) at baseline and 1.5 (SD 0.87) at six months.

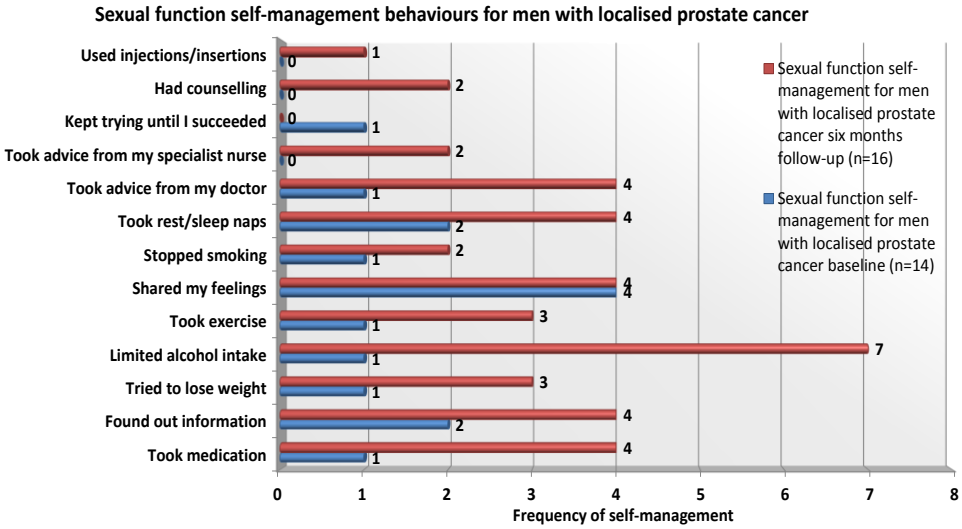


Figure 5.10 Distributions of sexual function self-management behaviours for men with localised prostate cancer

Fifteen men (51.7%) with locally advanced cancer performed sexual function self-management at baseline and sixteen men (55.2%) performed sexual function self-management at six months (see figure 5.13). The mean score for sexual function self-management relief for men with locally advanced cancer was 1.94 (SD 0.99) at baseline and 2.1 (SD 1.47) at six months.

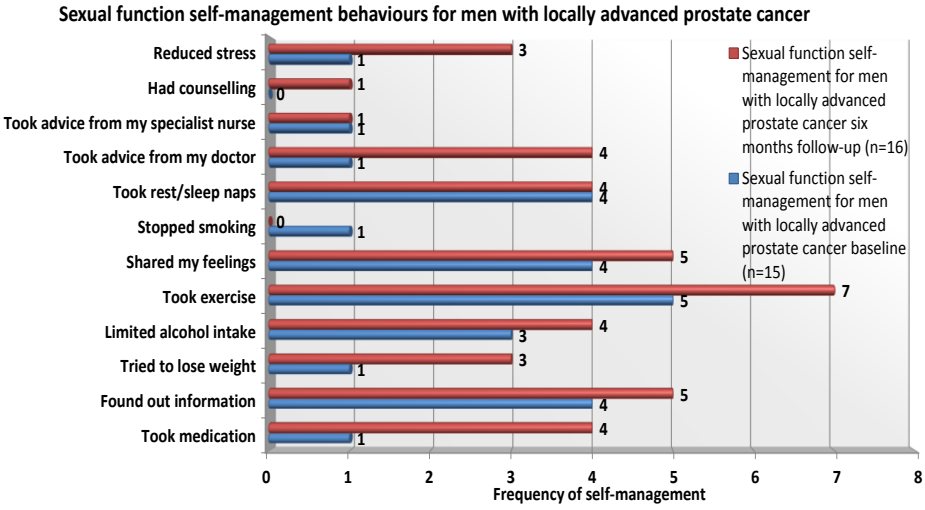


Figure 5.11 Distributions of sexual function self-management behaviours for men with locally advanced prostate cancer

Men with metastatic prostate cancer performed very little self-management for sexual function at baseline (28.6%, n=2) and at six months (57.1%, n=4) (see figure 5.14). At baseline, two men reported erectile dysfunction for which they performed

self-management, but one man did report his self-management behaviours. At six months, four men reported erectile dysfunction, but two participants did not provide data which described their sexual function self-management behaviours. The mean score for sexual function relief was 3.0 (SD.0) at baseline and 2.0 (SD.0) at six months.

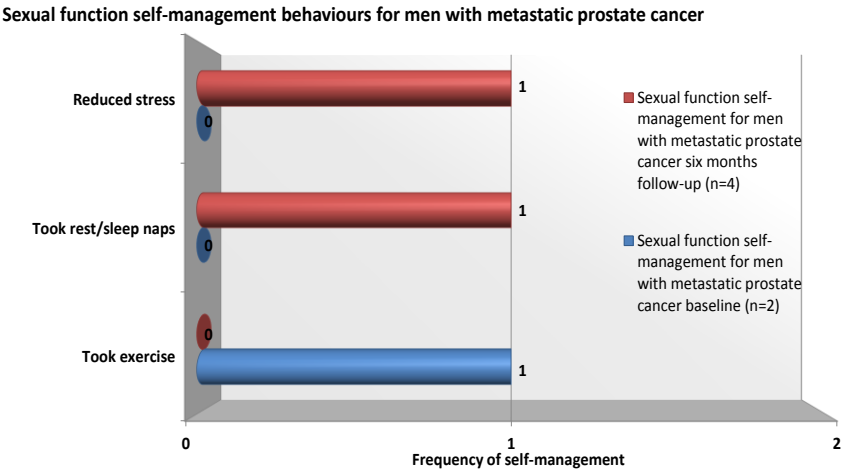


Figure 5.12 Distributions of sexual function self-management behaviours for men with metastatic prostate cancer

In summary, the number of men performing sexual function self-managment increased from baseline to six months. Men performed a variety of self-management actions, however these had little efficacy in improving erectyle dsyfunction.

Suggestions for self-management

The distributions of suggestions for self-management behaviours are idenitified in figure 5.15. Overall, men most received suggestions for self-management from their partners at baseline (n=32 [47.1%]) and at six months (n=42 [61.7%]). The second most frequent source of information for self-managenment actions were from doctors, and the least frequent source of information for self-management was from the physiotherapists and other cancer patients.

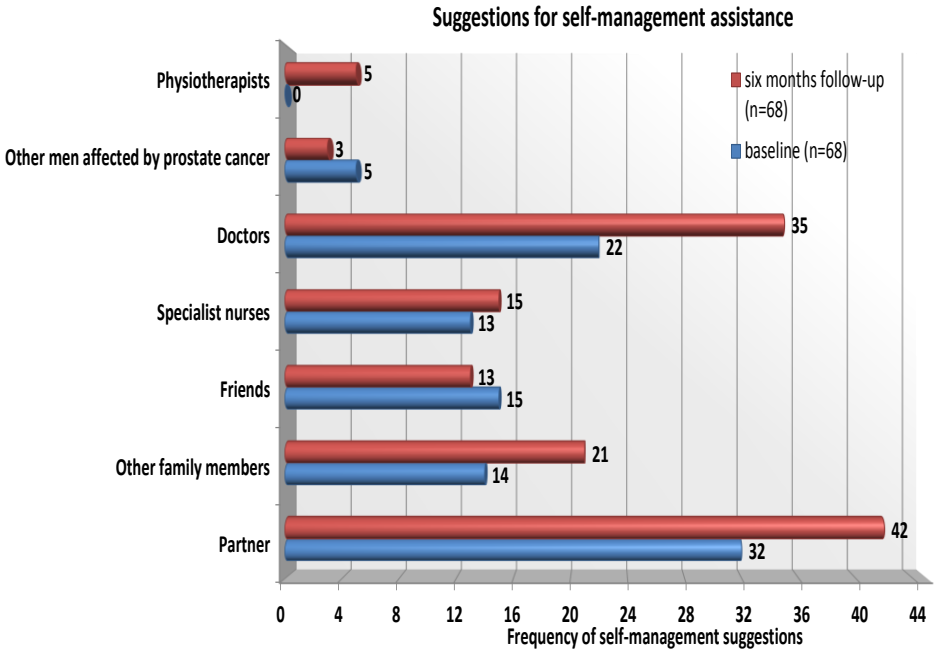


Figure 5.13 Distribution of suggestions for self-management behaviours for all participants (n=68)

5.5.8 Main, moderation and mediation effects of coping and social support on health-related quality of life, anxiety and depression at 6 months.

To address the third research question, a series of hierarchical multiple regression analyses were performed to tests for main, moderation and mediation effects of coping and social support at baseline on a) quality of life, b) anxiety, and c) depression at six months. Hierarchical multiple regression analysis was used because this methods assumes a theoretical or logical approach to the order in which variables are entered into the regression model. A bivariate correlation analysis was performed to identify univariate predictors for inclusion in the hierarchical multiple regression analysis. Variables at the less stringent $p<0.15$ were considered for inclusion (Tabachnick and Fidell, 2007) to ensure all potential predictors were included in the model.

Prior to the analysis the underlying assumptions were check according to suggestion by Tabachnick and Fidell (2007) and Field (2005) (see section 5.4.1). A detailed

explanation of the analytical steps performed to test for moderation and mediation effects are identified in chapter 4 (section 4.7.7).

Global quality of life $_{\text{square root}}$ at six months as the dependent variable

A bivariate correlation analysis was performed with global quality of life $_{\text{square root}}$ at six months and at all baseline variables. Prior to conducting the Pearson's product-moment correlations, preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. The results of the Pearson's product-moment correlation coefficients are details in table 5.17.

Table 5.17 Bivariate correlations with Global quality of life $_{\text{square root}}$ at six months and study variables at baseline

Baseline study variables	Global quality of life $_{\text{square root}}$ at six months
MAC Scale, positive coping	0.151
MAC Scale, negative coping	-0.182*
Perceived stress	-0.259**
Self-management self-efficacy	0.081
Received social support $_{\text{Square root}}$	-0.161
Perceived social support	0.348***
Satisfaction social support	0.350***
HADS, Anxiety $_{\text{Square root}}$	-0.086
HADS, Depression $_{\text{Log}}$	-0.236*
EORTC C30, Physical function	0.315***
EORTC C30, Role function	0.354***
EORTC C30, Emotional function	0.294**
EORTC C30, Cognitive function	0.258**
EORTC C30, Social function	0.350***
EORTC C30, Global quality of life $_{\text{Square root}}$	0.483***
EORTC C30, Nausea and vomiting	0.019
EORTC C30, Pain	-0.147
EORTC C30, Dyspnoea	-0.223*
EORTC C30, Insomnia	-0.160
EORTC C30, Appetite loss	-0.082
EORTC C30, Constipation	-0.290**
EORTC C30, Diarrhoea	-0.328***
EORTC C30, Fatigue $_{\text{Square root}}$	-0.468***
EORTC C30, Financial difficulties	-0.142
EORTC PR25, Urinary symptoms $_{\text{Square root}}$	-0.180*
EORTC PR25, Bowel symptoms	-0.330***
EORTC PR25, Treatment symptoms	-0.335***
EORTC PR25, Incontinence aid	-0.036
EORTC PR25, Sexual activity	0.182*
EORTC PR25, Sexual function	-0.184
Number of co morbidities	-0.168
Age	-0.260**
PSA $_{\text{square root}}$	-0.238*

*significant level p<0.15, ** significant level p<0.05, ***significant level p<0.01 (n=68)

Three baseline variables (global quality of life $_{\text{square root}}$, negative coping $_{\text{centred}}$ and perceived social support $_{\text{centred}}$) were entered in to the equation in three steps because of their central importance in addressing the third research question. Negative coping and perceived social support variables were centred and a product term was calculated to test for moderation effects, based on guidance from (Tabachnick and Fidell, 2007, Holmbeck, 2002, Aiken and West, 1991). At step one: baseline global quality of life $_{\text{square root}}$ was entered; at step two: negative coping $_{\text{centred}}$ and perceived social support $_{\text{centred}}$; and at step three: the product term for negative coping $_{\text{centred}}$*perceived social support $_{\text{centred}}$. The sample size (n=67) was just below the recommend sample size calculation (50+8m=74) (Tabachnick and Fidell, 2007) and therefore, adding additional predictors would have largely under powered the analysis. The limitations of this statistical approach will be addressed in the discussion. The results of the hierarchical multiple regression analysis are displayed in table 5.18.

Goodness of model fit was checked and was considered satisfactory and no multivariate outliners were identified. Collinearly statistics and Durbin-Watson test were acceptable and scatterplots indicate no violation of normality, linearity or homoscedasticity. Global quality of life $_{\text{square root}}$ (β=0.325, p=0.006) and perceived social support (β=0.272 p=0.016) at baseline had a statistically significant effect on global quality of life $_{\text{square root}}$ at six months. Negative coping at baseline did not significantly predict global quality of life at six months and no moderation effects were demonstrated. Model three explained 29.6% (adjusted R^2) of the variance of global quality of life at six months (see table 5.18).

A second hierarchical multiple regression analysis was performed with negative coping and satisfaction of social support on global quality of life $_{\text{square root}}$ at six months. The three baseline variables (global quality of life $_{\text{square root}}$, negative coping $_{\text{centred}}$ and satisfaction of social support $_{\text{centred}}$) were entered in to the equation in three steps because of their central importance in addressing the third research question. Negative coping and satisfaction of social support variables were centred and a product term was calculated to test for moderation effects. At step one: global quality of life $_{\text{square root}}$ were entered; at step two: negative coping $_{\text{centred}}$ and satisfaction of social support $_{\text{centred}}$; and at step three: the product term negative

coping $_{centred}$*satisfaction with social support $_{centred}$ was entered. The sample size was just below (n=67) the sample size calculation (50+8m=74) (Tabachnick and Fidell, 2007) and therefore, adding additional predictors would have largely under-powered the analysis. Prior to the analysis, the underlying assumptions were checked. The results of the hierarchical multiple regressions are displayed in table 5.19.

Goodness of model fit was checked and was considered satisfactory. Collinearly statistics and Durbin-Watson test were acceptable, no multivariate outliners identified, and scatterplots indicate no violation of normality, linearity or homoscedasticity. Satisfaction with social support (β=0.278 p=0.014) and global quality of life $_{square\ root}$ (β=0.401, p=0.001) at baseline had a statistically significant main effect on global quality of life $_{square\ root}$ at six months. Satisfaction with social support did not moderate the relationship between negative coping and global quality of life at six months. Model two explained 25.0% (adjusted R^2) of the variance of global quality of life at six months (see table 5.19).

Mediation effects of were not tested because negative coping at baseline was not a significant predictor of global quality of life $_{square\ root}$ at six months.

Table 5.18 Hierarchical multiple regression analysis with baseline global quality of life, negative coping and perceived social support scores at baseline on global quality of life $_{\text{square root}}$ at six months as the dependent variable

Model	R Square change	R	R^2	Adjusted R^2	B	SE B	β	Significance
One: Constant					3.468	1.147		0.004**
Baseline global quality of life $_{\text{square root}}$	.233	0.483	0.233	0.221***	0.575	0.129	0.483	0 .000***
Two: Constant					4.561	1.198		0.000***
Baseline global quality of life $_{\text{square root}}$	.068	0.548	0.300	0.267***	0.451	0.135	0.378	0.001**
Baseline Negative coping $_{\text{centred}}$					0.019	0.017	-0.118	0.267
Baseline Perceived social support $_{\text{centred}}$					0.223	0.094	0.266	0.021*
Three: Constant					5.117	1.211		0.000
Baseline global quality of life $_{\text{square root}}$	.038	0.582	0.338	0.296***	0.387	0.137	0.325	0.006**
Baseline Negative coping $_{\text{centred}}$					-0.019	0.017	-0.118	0.267
Baseline Perceived social support $_{\text{centred}}$					0.228	0.092	0.272	0.016*
Baseline Negative coping $_{\text{centred}}$ X Perceived social support $_{\text{centred}}$					0.026	0.014	0.202	0.064

*significant level p<0.05, ** significant level p<0.01, ***significance level p<0.001 (n=67)

Table 5.19 Hierarchical multiple regression analysis with global quality of life, negative coping and satisfaction of social support scores at baseline on global quality of life $_{\text{square root}}$ at six months as the dependent variable

Model	R Square change	R	R^2	Adjusted R^2	B	SE B	β	Significance
One: Constant					3.395	1.278		0.010**
Baseline Global quality of life $_{\text{square root}}$	.208	0.456	0.208	0.195***	0.582	0.148	0.456	0.000***
Two: Constant					4.010	1.270		0.002*
Baseline Global quality of life $_{\text{square root}}$	.078	0.534	0.286	0.250**	0.513	0.142	0.401	0.001**
Baseline Negative coping $_{\text{centred}}$					-0.006	0.017	-0.038	0.733
Baseline Satisfaction of social support $_{\text{centred}}$					0.687	0.273	0.278	0.014*
Three: Constant					4.048	1.310		0.003
Baseline Global quality of life $_{\text{square root}}$	.000	0.535	0.286	0.238	0.509	0.146	0.398	0.001**
Baseline Negative coping $_{\text{centred}}$					-0.007	0.018	-0.042	0.716
Baseline Satisfaction social support $_{\text{centred}}$					0.650	0.380	0.263	0.092
Baseline Negative coping $_{\text{centred}}$ X Satisfaction of social support $_{\text{centred}}$					0.009	0.067	0.022	0.889

*significant level p<0.05, ** significant level p<0.01, ***significant level p<0.001 (n=67)

Anxiety $_{\text{square root}}$ at six months as the dependent variable

A bivariate correlation analysis was performed with anxiety $_{\text{square root}}$ at six months and all baseline variables. Prior to conducting the Pearson's product-moment correlations, preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. The results of the Pearson's product-moment correlation coefficients are details in table 5.20.

Table 5.20 Bivariate correlations with anxiety $_{\text{square root}}$ at six months and study variables at baseline

Baseline study variables	Anxiety $_{\text{square root}}$ at six months
MAC Scale, positive coping	-0.083
MAC Scale, negative coping	0.512***
Perceived stress	0.478***
Self-management self-efficacy	-0.026
Received social support $_{\text{Square root}}$	0.124
Perceived social support	0.169
Satisfaction social support	-0.201*
HADS, Anxiety $_{\text{Square root}}$	0.454***
HADS, Depression $_{\text{Log}}$	0.263**
EORTC C30, Physical function	-0.010
EORTC C30, Role function	-0.205*
EORTC C30, Emotional function	-0.579***
EORTC C30, Cognitive function	-0.257**
EORTC C30, Social function	-0.342***
EORTC C30, Global quality of life $_{\text{Square root}}$	-0.278**
EORTC C30, Nausea and vomiting	0.240**
EORTC C30, Pain	0.012
EORTC C30, Dyspnoea	0.051
EORTC C30, Insomnia	0.412***
EORTC C30, Appetite loss	0.129
EORTC C30, Constipation	0.208*
EORTC C30, Diarrhoea	0.188*
EORTC C30, Fatigue $_{\text{Square root}}$	0.229*
EORTC C30, Financial difficulties	0.112
EORTC PR25, Urinary symptoms $_{\text{Square root}}$	0.061
EORTC PR25, Bowel symptoms	0.317**
EORTC PR25, Treatment symptoms	0.346***
EORTC PR25, Incontinence aid	0.046
EORTC PR25, Sexual activity	0.067
EORTC PR25, Sexual function	0.070
Number of co morbidities	0.076
Age	-0.012
PSA $_{\text{square root}}$	-0.120

*significant level p<0.15, ** significant level p<0.05, ***significant level p<0.01 (n=68)

Three baseline variables (anxiety $_{\text{square root}}$, negative coping $_{\text{centred}}$ and satisfaction with social support $_{\text{centred}}$) were entered in to the equation in three steps because of their

central importance in addressing the third research question. Negative coping and satisfaction with social support variables were centred and a product term was calculated to test for moderation effects. At step one: anxiety $_{\text{square root}}$ was entered; at step two: negative coping $_{\text{centred}}$ and satisfaction with social support $_{\text{centred}}$; and at step three: the product term negative coping $_{\text{centred}}$*satisfaction with social support $_{\text{centred.}}$ The sample size was just below (n=67) the sample size calculation (50+8m=74) (Tabachnick and Fidell, 2007) and therefore, adding additional predictors would have largely under-powered the analysis. The results of the hierarchical multiple regression analysis are displayed in table 5.21.

Goodness of model fit was checked and was considered satisfactory. Collinearly statistics and Durbin-Watson test were acceptable, no multivariate outliners identified, and scatterplots indicate no violation of normality, linearity or homoscedasticity. After controlling for baseline anxiety $_{\text{square root}}$ scores, negative coping at baseline was a significant predictor of anxiety $_{\text{square root}}$ (β=0.359, p=0.010). Satisfaction with social support at baseline did not demonstrate main or moderating effects with negative coping on anxiety $_{\text{square root}}$ scores at six months. Model two explained 28.5% (adjusted R^2) of the variance of anxiety $_{\text{square root}}$ at six months (see table 5.21).

Mediation effects were not tested because satisfaction with social support at baseline was not a significant predictor of global quality of life $_{\text{square root}}$ at six months.

Table 5.21 Hierarchical multiple regression analysis with anxiety, negative coping and satisfaction of social support scores at baseline on anxiety $_{\text{square root}}$ at six months as the dependent variable

Model	R Square change	R	R^2	Adjusted R^2	B	SE B	β	Significance
One: Constant					1.045	0.286		0.001**
Baseline Anxiety $_{\text{square root}}$	.221	0.470	0.221	0.209***	0.515	0.121	0.470	0.000***
Two: Constant					1.637	.342		.000***
Baseline Anxiety $_{\text{square root}}$	.097	0.564	0.318	0.285**	0.250	0.147	0.229	0.094
Baseline Negative coping $_{\text{centred}}$					0.043	0.016	0.359	0.010*
Baseline Satisfaction with social support $_{\text{centred}}$					-0.240	0.209	-0.127	0.236
Three: Constant					1.693	0.364		0.000***
Baseline Anxiety $_{\text{square root}}$	.002	0.566	0.320	0.275	0.222	0.160	0.203	0.170
Baseline Negative coping $_{\text{centred}}$					0.046	0.018	0.389	0.012*
Baseline Satisfaction with social support $_{\text{centred}}$					-0.150	0.299	-0.076	0.618
Baseline Negative coping $_{\text{centred}}$ X Satisfaction with social support $_{\text{centred}}$					-0.026	0.054	-0.076	0.638

*significant level p<0.05, ** significant level p<0.01, ***significant level p<0.001 (n=67)

Depression $_{log}$ at six months as the dependent variable

A bivariate correlation analysis was performed with depression $_{log}$ at six months and all baseline variables. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. The results of the Pearson's product-moment correlation coefficients are details in table 5.22.

Table 5.22 Bivariate correlations with depression $_{log}$ at six months and study variables at baseline

Baseline study variables	depression $_{log}$ at six months
MAC Scale, positive coping	-0.034
MAC Scale, negative coping	0.415***
Perceived stress	0.321***
Self-management self-efficacy	-0.138
Received social support $_{Square\ root}$	0.172
Perceived social support	-0.223*
Satisfaction social support	-0.234*
HADS, Anxiety $_{Square\ root}$	0.252**
HADS, Depression $_{Log}$	0.306**
EORTC C30, Physical function	-0.292**
EORTC C30, Role function	-0.357***
EORTC C30, Emotional function	-0.442***
EORTC C30, Cognitive function	-0.338***
EORTC C30, Social function	-0.388***
EORTC C30, Global quality of life $_{Square\ root}$	-0.419***
EORTC C30, Nausea and vomiting	0.128
EORTC C30, Pain	0.123
EORTC C30, Dyspnoea	0.198*
EORTC C30, Insomnia	0.357***
EORTC C30, Appetite loss	0.094
EORTC C30, Constipation	0.105
EORTC C30, Diarrhoea	0.247**
EORTC C30, Fatigue $_{Square\ root}$	0.324***
EORTC C30, Financial difficulties	0.139
EORTC PR25, Urinary symptoms $_{Square\ root}$	0.101
EORTC PR25, Bowel symptoms	0.355***
EORTC PR25, Treatment symptoms	0.263**
EORTC PR25, Incontinence aid	0.098
EORTC PR25, Sexual activity	0.056
EORTC PR25, Sexual function	0.148
Number of co morbidities	0.211*
Age	0.249**
PSA $_{square\ root}$	-0.141

*significant level p<0.15, ** significant level p<0.05, ***significant level p<0.01 (n=68)

Three baseline variables (depression $_{log}$, negative coping $_{centred}$ and satisfaction with social support $_{centred}$) were entered in to the equation in three steps because of their central importance in addressing the third research question. Negative coping and satisfaction with social support variables were centred and a product term was

calculated to test for moderation effects. At step one: depression $_{log}$ was entered; at step two: negative coping $_{centred}$ and satisfaction with social support $_{centred}$; and at step three: the product term negative coping $_{centred}$*satisfaction with social support $_{centred}$ was entered. The sample size was just below (n=67) the sample size calculation (50+8m=74) (Tabachnick and Fidell, 2007) and therefore, adding additional predictors would have largely under-powered the analysis. The results of the hierarchical multiple regression analysis are displayed in table 5.23.

Goodness of model fit was checked and was considered satisfactory. Collinearly statistics and Durbin-Watson test were acceptable, no multivariate outliners identified, and scatterplots indicate no violation of normality, linearity or homoscedasticity. After controlling for baseline depression $_{log}$ scores, negative coping at baseline was a significant predictor of depression $_{log}$ (β=0.337, p=0.007) at six months. Satisfaction with social support at baseline did not demonstrate a main on depression scores at six months. Furthermore, satisfaction with social support did not moderate the relationship between negative coping and depression $_{log}$ at six months. Overall, model two explained 19.5% (adjusted R^2) of the variance of depression $_{log}$ at six months (see table 5.23). Mediation effects were not tested because satisfaction with social support at baseline was not a significant predictor of depression $_{log}$ at six months.

A second hierarchical multiple regression analysis was performed with negative coping and perceived social support on depression $_{log}$ at six months. The three baseline variables (depression $_{log}$, negative coping $_{centred}$ and perceived social support $_{centred}$) were entered in to the equation in three steps because of their central importance in addressing the third research question. Negative coping and perceived social support variables were centred and a product term was calculated to test for moderation effects. At step one: depression $_{log}$; at step two: negative coping $_{centred}$ and perceived social support $_{centred}$; and at step three: the product term negative coping $_{centred}$*perceived social support $_{centred}$ was entered. The sample size was just below (n=67) the sample size calculation (50+8m=74) (Tabachnick and Fidell, 2007) and therefore, adding additional predictors would have largely under-powered the analysis. Prior to the analysis, the underlying assumptions were checked. The results of the hierarchical multiple regressions are displayed in table 5.24.

After controlling for baseline depression $_{log}$ scores, negative coping (β=0.381, p=0.002) and perceived social support (β=-0.243, p=0.029) at baseline had a significant main effects and explained 22.3% (adjusted R^2) of the variance of depression $_{log}$ scores at six months. Perceived social support did not moderate the relationship between negative coping and depression, p>0.05. Mediation effects were not possible because perceived social support and negative coping scores at baseline were not significantly related (β -0.077, p=0.534).

Table 5.23 Hierarchical multiple regression analysis with depression, negative coping and satisfaction with social support scores at baseline on depression $_{log}$ at six months as the dependent variable

Model	R Square change	R	R^2	Adjusted R^2	B	SE B	β	Significance
One: Constant					0.384	0.068		0.000***
Baseline Depression $_{log}$	.093	0.305	0.093	0.079*	0.307	0.120	0.305	0.013*
Two: Constant					0.454	0.068		0.000***
Baseline Depression $_{log}$	.139	0.482	0.232	0.195**	0.165	0.121	0.163	0.178
Baseline Negative coping $_{centred}$					0.015	0.005	0.337	0.007**
Baseline Satisfaction with social support $_{centred}$					-0.132	0.082	-0.180	0.114
Three: Constant					0.462	0.069		0.000***
Baseline Depression $_{log}$	.007	0.489	0.239	0.189	0.138	0.127	0.137	0.279
Baseline Negative coping $_{centred}$					0.016	0.006	0.370	0.006**
Baseline Satisfaction with social support $_{centred}$					-0.076	0.117	-0.097	0.544
Baseline Negative coping $_{centred}$ X Satisfaction with social support $_{centred}$					-0.015	0.021	-0.120	0.466

*significant level p<0.05, ** significant level p<0.01, ***significant level p<0.001 (n=67)

Table 5.24 Hierarchical multiple regression analysis with depression, negative coping and perceived of social support scores at baseline on depression $_{log}$ at six months as the dependent variable

Model	R Square change	R	R^2	Adjusted R^2	B	SE B	β	Significance
One: Constant					0.386	0.069		0.000***
Baseline Depression $_{log}$	.094	0.306	0.094	0.080*	0.315	0.121	0.306	0.011*
Two: Constant					0.456	0.067		0.000***
Baseline Depression $_{log}$	.165	0.508	0.258	0.223**	0.154	0.120	0.150	0.203
Baseline Negative coping $_{centred}$					0.017	0.005	0.381	0.002**
Baseline Perceived social support $_{centred}$					-0.054	0.026	-0.243	0.029*
Three: Constant					0.476	0.066		0.000***
Baseline Depression $_{log}$	.041	0.547	0.299	0.254	0.141	0.117	0.137	0.234
Baseline Negative coping $_{centred}$					0.017	0.005	0.378	0.002**
Baseline Perceived social support $_{centred}$					-0.059	0.026	-0.243	0.026*
Baseline Negative coping $_{centred}$ X Perceived social support $_{centred}$					-0.007	0.004	-0.202	0.060

*significant level p<0.05, ** significant level p<0.01, ***significant level p<0.001 (n=67)

5.6 Discussion

This prospective longitudinal survey was acceptable for the participants because there was very little attrition and missing data. The standardised measures used were reliable and valid. No selection bias was demonstrated between the participants who did not consent to take part in the study for age, cancer stage and treatment. The response rate for the study was 67.9% and this result is similar to that reported by van de Poll-Franse et al. (2008b), Fransson (2008), Diefenbach and Mohamed (2007), and Miller et al. (2007). Six men (8.1%) were lost from the study at the six months data collection and they were more likely to be older. The sample sizes for the five regression analyses were marginally below the recommended sample size based the on guidance from Tabachnick and Fidell (2007) and therefore, some caution should be taken in the interpretation of the findings. Each regression model explained approximately 30% of the variance of the dependent variables (Anxiety $_{\text{square root}}$, depression $_{\text{log,}}$ and global quality of life $_{\text{square root}}$) which left a proportion of variance unexplained by the model and is similar to that reported elsewhere (Zhou et al., 2010a, Roberts et al., 2006). The number of independent variables entered into the analyses could have been increased but this would have caused the analyses to be significantly underpowered. Therefore, acknowledging additional variables (such as symptoms, co-morbidity, age, etc.) may have had a significant multivariate contribution; the five regression analyses performed controlled for appropriate baseline variables to test the social support theoretical model and were sufficiently powered.

The HADS (Snaith and Zigmond, 1986) was acceptable to participants and had very little missing data. No statistically significant difference was found in the means scores for anxiety and depression scores at baseline and at six months. The mean score for anxiety and depression at baseline (4.62 & 2.88) and at six months (4.53 & 3.32) are similar to published studies (Berglund et al., 2007, Ene et al., 2006, Brindle et al., 2006). Using the cut-off scores (Zigmond and Snaith, 1983) at baseline, 7.4% of men were identified as having possible/probable depression and 10.3% of men at six months. An (arbitrary) trend of increased depression at six months is not surprising because men can face a host of problems which may affect their emotional outcome.

Negative coping and perceived social support at baseline had a significant main effect on depression at six months. This provides support the main effect theoretical model (Cohen and Wills, 1985) because participants who reported high perceived social support at baseline (β=-0.243, p=0.026) had lower depression scores at six months. There were no associations with received social support and satisfaction with social support variables at baseline with depression scores at six months. These data demonstrate that perceived social support is a longitudinal predictor of emotional outcome and this is in keeping with published studies (Zhou et al., 2010a, Roberts et al., 2006). On closer scrutiny, Zhou and Roberts investigated the effects of perceived social support only; therefore the findings in the present study add an important perspective on the support processes for emotional outcome. When considering the following social support constructs: received social support, perceived social support and satisfaction of social support, perceived social support was the most important social support predictor of depression at six months.

Depression scores (at six months) were negatively correlated with all of the EORTC functional scales (physical function, role function, emotional function, cognitive function and social function at baseline) and this is similar to data presented by Ene et al. (2006). Depression (at six months) also had a number of positive associations with the following variables at baseline: perceived stress, insomnia, fatigue, treatment symptoms, bowel symptoms and age, and these associations have been demonstrated in published studies (Monahan et al., 2007, Ene et al., 2006, Monga et al., 2005). The significant correlations between the baseline variables and depression at six months in the aforementioned results could have been entered into the regression equation; however this would have increased the number of independent variables and resulted in reduced statistical power due to a small sample size. Approximately 70% of the variance of depression scores at six months was not accounted for by the following baseline variables: depression scores, negative coping and perceived social support. Therefore, further study with a larger sample size would be helpful to explore the influences of such variables on depression scores over time.

After controlling for baseline anxiety scores, baseline negative coping (β=0.359, p=0.010) was a significant longitudinal predictor of anxiety scores at six months.

Received social support and perceived social support variables had no association with anxiety at six months. Satisfaction with social support was entered into the regression equation at $p<0.15$, and did not significantly predict anxiety scores at six months. Therefore, social support variables (perceived, received and satisfaction with social support) did not have any main or moderation (buffering) effects, and mediation was not tested because the conditions for mediation analysis were not met. These data do not support existing theoretical models (main effects and stress buffering) linking social support to anxiety and the reasons as to why are not clear. Previous cross-section studies have identified an association between perceived social support and anxiety (Balderson and Towell, 2003) for men affected by prostate cancer, but such retrospective cross-sectional designs are prone to bias. Such designs cannot identify a causal pathway linking social support to emotional outcome over time, specifically, cross-sectional designs cannot determine facts about "time order" of social support and anxiety; in other words, whether one variable preceded the other. This Ph.D. study has identified that baseline social support constructs do not significantly predict anxiety score at six months.

Global quality of life (EORTC C30) at six months was positively associated with the EORTC C30 functional scales and negatively related to individual symptoms scales. The hierarchical multiple regression analysis demonstrated longitudinal predictors of global quality of life at six months with the following baseline variables: global quality of life, perceived social support and satisfaction with social support. The correlation coefficients identified baseline positive coping had no association with quality of life at six months, and negative coping was entered in to the regression equation at $p<0.15$, but did not significantly predict global quality of life. Baseline global quality of life ($\beta=0.325$, $p=.006$) and perceived social support ($\beta=0.272$, $p=0.016$) explained 29.6% (adjusted R^2) of the variance of global quality of life at six months. Whereas, baseline global quality of life ($\beta=0.401$, $p=0.001$) and satisfaction with social support ($\beta=0.278$, $p=0.014$) explained 25.0% (adjusted R^2) of the variance of global quality of life at six months. These data identify that perceived social support explained a slightly greater proportion of the variance of global quality of life compared to the satisfaction with social support construct. These data support the main effect theoretical model for perceived and satisfaction with social support on global quality of life. Received social support was insufficiently associated with global quality of

life, and therefore did not meet the criteria to be entered into the regression equation. There were no moderation (buffering) effects with negative coping, and a) perceived social support, and b) satisfaction with social support, and the conditions for mediation analysis did not hold.

The findings identified that baseline positive coping and received social support had no relationship with anxiety, depression and global quality of life at six months. Baseline perceived social support was found to have a main effect on depression and global quality of life at six months, and baseline satisfaction with social support had a main effect on global quality of life at six months only. Therefore, negative coping, perceived social support and satisfaction with social support were the most important longitudinal predictors of global quality of life and depression at six months. These analyses did not demonstrate any moderating (buffering effects) or mediating effects with negative coping and social support (perceived and satisfaction with social support) on the dependent variables. These data support that perceived social support and satisfaction with social support had a positive influence on health-related outcomes regardless of the level of negative coping scores. These data support the main effect theoretical model (Cohen and Wills, 1985) based on aggregate group level effects and is in keeping with published studies (Zhou et al., 2010a, Zhou et al., 2010b, Queenan et al., 2010, Kershaw et al., 2008, Visser et al., 2003, Rondorf-Klym and Colling, 2003). Overall, perceived social support was the most important social support construct that predicted depression and health-related quality of life.

There was little change in perceived social support at baseline and at six months follow-up (t=-1.42, ns) and suggests that perceptions of availability of social support are relatively stable over time; this is in keeping with the work of Sarason et al. (1986). Received social support significantly increased over time (t=-2.10, p=0.031) with no change in satisfaction with social support over time (t=1.00, ns). Descriptive data suggested an overall trend of increased usage of additional cancer support services, but the large majority of men did not engage with additional cancer support services at baseline or at six months follow-up. These data are consistent with those published by Krizek et al. (1999), demonstrating that a minority of men will engage with additional support services, leaving a substantial percentage of men who do not

use additional support services. It maybe that the majority of men are, a) not interested in such support services, b) men feel that such services do not meet their care needs, or c) men have a negative attitude towards support services. The current study identified less than 20% of men participated in additional cancer support services, such as Maggie's Cancer Care Centre and this is similar to the data published by (Shapiro et al., 2004) who reported 22% of men expressed an interest in cancer support services, such as peer support. Data have demonstrated factors that influence men's participation in additional cancer support services and these include the following variables: lower age, higher socio-economic status, low perceived social support and a positive attitude towards receiving additional cancer support (Voerman et al., 2007). The current study did not explore determinates of participation in additional cancer support services and this element would be worthy of further research.

The mean score for received social support was 1.68 (SD 0.40) at one month following a prostate cancer diagnosis and 1.97 (SD 0.99) at six months follow-up. The total possible maximum mean score is 4.0, indicating that men scored almost half of the total maximum mean score for the received social support scale. Cancer studies that have previously used the BSSS in cancer populations identify that men in this current study scored consistently less on the received social support scale overtime when compared to published data (Boehmer et al., 2007, Luszczynska et al., 2007a, Schwarzer et al., 2006, Luszczynska et al., 2005). Previous studies have reported the mean score for received social support >3.70 in cancer populations using this instrument. There are several possible explanations to account for men reporting less received social support compared to previously published data. The published studies (Boehmer et al., 2007, Luszczynska et al., 2007a, Schwarzer et al., 2006, Luszczynska et al., 2005) were limited to cancer participants undergoing surgery only, therefore it is possible, due to the invasive nature of surgery, that participants consistently reported a higher amount of received social support. This current study consisted of a heterogeneous population of men with different treatment modalities, with nine men treated by surgical techniques. However, no statistical association with cancer treatment and level of received social support was demonstrated using a one-way between group analysis of variance, and thus would seem an unlikely explanation. From the reviewed studies, the samples had mixed cancer sites, mixed

gender and the samples were non-UK. Different cancer sites, gender and cultural differences could influence support provision, furthermore, social support may affect specific cancer populations in unique ways, given the distinct physical and psychological challenges associated with each cancer (Zhou et al., 2010a). Thus, additional research would be helpful to advance understanding in this area.

The EORTC C30 and PR25 were well accepted by participants and had very little missing data. Reliability was acceptable for all scales except for cognitive function (>0.55), bowel symptoms (>0.51) and treatment symptoms (>0.41). It could be that these scales performed poorly in this the study sample. The Cronbach's alpha coefficients reported here demonstrate similar reliability coefficients to that of several recently published studies (Roeloffzen et al., 2010, Vordermark et al., 2009, van Andel et al., 2008, Lips et al., 2007, Spry et al., 2006).

There were a number of statistically significant changes in health-related quality of life at six months. Global quality of life significantly decreased at six months follow-up ($t=2.35$, $p=0.021$). There were no significant changes in the functional scales (role function, cognitive function, emotional function and social function) except for a significant decrease in physical function at six months. A number of statistically significant increases over time were identified for fatigue, constipation and appetite loss, but no change was demonstrated for the following symptoms: dyspnoea, pain, diarrhoea, and financial difficulties. Osoba et al. (1999) suggest that a change of ≥20 points on a standardised measure (scale range of 0-100) represents a clinically large change, a change of 10-20 points indicates a moderate change, and 5-10 points is indicative of a small clinical change. The guidelines from Osoba have been applied to published prostate cancer studies (Lips et al., 2009, Stephens et al., 2007, Buron et al., 2007, Lips et al., 2007, Spry et al., 2006), and are useful to understand the clinical relevance of HRQoL data for the current study. Using the guidance from Osoba, global quality of life scores reduced over time and showed a small clinically relevant change (score change >5.2, on a 0-100 scale); this is similar to the results of Buron et al. (2007).

There were no statistically significant changes in the functional scales apart from the physical function scores at six months, which reduced over baseline scores and was

approaching a small clinical change (score difference >4.96, on a 0-100 scale). This result is in keeping with existing studies that have demonstrated very little deterioration or change in scores over time for functional domains of quality of life for prostate cancer survivors (Hashine et al., 2009, Kato et al., 2007, Namiki et al., 2006b, Robinson et al., 1999a). Appetite loss, constipation and fatigue were significantly worse over time at six months. The score changes for the three symptoms as follows: appetite loss (score difference >4.48), constipation (score difference >4.91), fatigue (score difference >2.32) and were not clinically significant <5 (0-100 scale), and other researchers have published similar findings (Lips et al., 2009, Spry et al., 2006, Robinson et al., 1999a).

Overall, the results in the current study appear to be consistent with others. Due to the limited follow-up period, it was not possible to assess for changes in HRQoL beyond six months, to confirm whether the population would have returned to baseline scores by twelve months. However, studies with longer follow-ups identify that differences in global quality of life scores are no longer statistically significant or clinically relevant at twelve months (Lips e al., 2009, Spry et al., 2006). The recovery of global quality of life would remain unknown for the current population in this study, but these data suggest recovery may be possible around twelve months.

Statistically significant increases were identified for bowel symptoms and treatment symptoms at six months, but not for urinary symptoms; this result was similar to the findings of Diefenbach and Mohamed (2007). The change in scores represent a small clinically significant change for bowel (>5.61) and treatment symptoms (>7.79) at follow-up, and these are similar to Lips et al., (2007). Sexual activity also statistically ($t=-1.74$, $p<0.05$) reduced over time and represented a small clinically significant change (<6.1). At one month after diagnosis, twenty-eight (41.2%) men were sexually active and at six months, fifteen men (22.1%) were sexually active. Reduced sexual activity for men living with prostate cancer has been widely demonstrated in published studies assessing change over time (Roeloffzen et al., 2010, Smith et al., 2009, Nguyen et al., 2009, Davison et al., 2007, Kato et al., 2007, Namiki et al., 2007, Jayadevappa et al., 2006, Feigenberg et al., 2005).

In keeping with the clinically relevant and statistically significant increase in bowel symptoms at six months, a statistically significant increase in bowel self-management was also identified at six months (McNemar's test p=0.002). The overall percentage of men who performed bowel self-management increased from 14.9% at baseline to 30.9% of men at six months. There were few men with localised disease who performed bowel self-management at baseline (two men) and at six months (four men). Men with localised prostate cancer performed a number of bowel self-management behaviours such as: "changed diet", "increased fluid intake", "shared thoughts and feelings", "took rest/sleep" and "took advice from a continence advisor". For men with localised prostate cancer, their self-management behaviours did not provide complete bowel symptom relief, but overall the percentage of men who performed bowel self-management was low at baseline (6.2%) and at six months (12.5%).

Bowel self-management was most frequently reported by men who had locally advanced prostate cancer in comparison to men with localised or metastatic disease. This was an expected result because locally advanced prostate cancer is often treated with neoadjuvant hormone therapy and radiotherapy (Stephens et al., 2007). Radiotherapy can cause bowel problems as an after-effect of this treatment. A large body of prospective data have demonstrated an increase in bowel problems following radiotherapy (Fransson et al., 2009a, Thong et al., 2009, Guedea et al., 2009, Pinkawa et al., 2009a, Robinson et al., 2009, Lips et al., 2009, Choo et al., 2007, Jayadevappa et al., 2006, Namiki et al., 2004) and would therefore explain the trend of increased bowel self-management for men with locally advanced disease. Of the men who were diagnosed with locally advanced cancer, five men (17.2%) performed bowel self-management behaviours at baseline and eleven (37.9%) men performed bowel self-management behaviours at six months. The increase in bowel self-management behaviours is similar to that reported by (Wilson et al., 2010); however, Wilson did not report participants' perceived effectiveness of the self-management strategies performed by the participants. Therefore, unfortunately, it is not possible to compare these data. For the participants who performed bowel self-management with locally advanced prostate cancer, the mean score for perceived effectiveness of self-management behaviours was 2.72 (SD.83) at baseline and 3.33 (SD.58) at six months. A trend of improved symptom relief was observed over time, but

participants did not achieve complete relief of their bowel problems through their self-management actions.

Similarly, men with metastatic disease did not achieve complete relief from their bowel self-management over time, and the number of men performing bowel self-care increased from two men at baseline to six men at follow-up. Several trends were common across all stages of cancer; firstly the number of men performing bowel self-care increased at six months, secondly men performed a number of self-management behaviours across all stages of cancer, and lastly, data indicate that men did not achieve complete relief of bowel problems from their self-management behaviours.

The overall percentage of men performing urinary self-management statistically reduced from 51.5% at baseline to 38.6% at six months. Men diagnosed with localised and locally advanced prostate cancer performed a great variety of urinary self-management behaviours compared to men with metastatic disease. It is important to acknowledge that there were few men with metastatic cancer in the study (nine men, 12.2%) and therefore, may not be representative of all men with metastatic cancer. The urinary self-management behaviours reported by men across all stages of disease included the following examples: “increased fluid intake”, “reduced caffeine intake”, “used pads”, “avoided heavy lifting” and “took medication”. For men with localised prostate cancer the number of men who performed urinary self-management reduced from fifteen men (46.8%) at baseline, to ten men (31.2%) at follow-up. A similar trend was identified for men with locally advanced and metastatic cancer, whereby the number of men performing urinary self-management reduced over time. This result is in keeping with published studies that have identified an improvement in urinary dysfunction over time (Sanda et al., 2008, Choo et al., 2007, Brar et al., 2005), and thus the number of men performing urinary self-management could be assumed to reduce over time.

The overall percentage of men performing self-management for sexual dysfunction increased over time from 45.6% of men at baseline, to 52.9% of men at six months, but this result was not statistically significant. Across all stages of cancer the number of men performing self-management for sexual dysfunction increased. Men

reported a number of strategies to improve their sexual function and examples included the following: “took medication”, “took rest”, “limited alcohol intake”, shared my thoughts and feelings”, “found out information” and “took advice from the doctor”. Men (all stages) reported little relief from their sexual function self-management behaviours. Based on the stage of cancer the mean scores at six months for sexual function self-management relief are as follows: for men with localised disease the mean score was 1.5 (SD.87), for men with locally advanced cancer 2.1 (SD 1.47), and for men with metastatic cancer 2.0 (SD 0). The total maximum mean score possible was 5.0, which would indicate complete relief of problems based on self-management actions, and thus men consistently reported little relief from their self-management across all stages of prostate cancer. Common to all stages of disease and treatment modalities is a worsening sexual function for a man living with prostate cancer. This finding has been widely demonstrated in the literature (Roeloffzen et al., 2010, Smith et al., 2009, Lips et al., 2009, Robinson et al., 2009, Diefenbach et al., 2008, Diefenbach and Mohamed, 2007, Davison et al., 2007, Buron et al., 2007, Kato et al., 2007, Jayadevappa et al., 2006, Jayadevappa et al., 2005, Monga et al., 2005), therefore, it is not surprising that men report an increase in sexual function self-management over time. But what is interesting, is that, despite a large number of self-management strategies used, men, unfortunately, do not have much improvement in their sexual function.

In summary, men with prostate cancer can perform a number of self-management behaviours for urinary, bowel and sexual dysfunction, often with little relief in alleviating their symptoms over time. In addition, self-management self-efficacy scores at six months were significantly reduced ($t=3.17$, $p=0.002$) compared to baseline. This finding suggests that prostate cancer survivors experience a decline in their belief to perform self-management with confidence and ease over time. Interestingly, men reported a greater number of suggestions for their self-management from “others” at six months. The most frequent source of self-management suggestions came from men’s partners and their doctors at both baseline and at six months. There are several possible explanations for the lower self-management self-efficacy scores over time. One explanation could be because men frequently reported receiving self-management suggestions from their partners, and the assistance provided could have been from an overprotective individual, and

thus reduced men's autonomy, thereby making them feel incapable of self-managing their condition. A further explanation might be, because men performed a number of self-management strategies which often, did not completely relieve the problems/symptom experienced, this could lower/reduced men's beliefs in their confidence and how easy they find their self-management. This area is worthy of further research to advance understanding of self-management self-efficacy over time.

5.7 Conclusion

This prospective longitudinal survey evaluated change over time and tested existing theoretical social support models linking support to health outcomes. The measures used in this study were reliable and had very little missing data. This study used a multi-dimensional assessment of social support which identified that perceived social support was the most important predictor of global quality of life and depression at six months. Satisfaction with social support at one month after a prostate cancer diagnosis had a main effect on depression scores at six months. This study provided support for the main effects model for certain aspects of social support, but did not demonstrate moderating (buffering) or mediation effects of social support with negative coping on health outcomes in this patient group. Received social support at baseline did not have any association with the dependent variables, and would suggest that perceptions of availability of help are more important that objective accounts of social support received.

No statistically significant changes were identified over time in anxiety and depression scores. Global quality of life demonstrated a clinically small relevant and statistically significant decrease at six months, but functional domains of health-related quality of life were mostly unaffected. Disease-specific domains of health-related quality of life were affected in this population and an increase in bowel and sexual dysfunction was identified at six months.

In keeping with the increase in bowel and sexual dysfunction at six months, the number of men performing bowel and sexual function self-management behaviours increased. The self-management data presented from this longitudinal survey have demonstrated an important insight into the self-management behaviours for men

living with this condition. Two key finding emerged from the self-management data. Firstly, men performed a number of self-management behaviours but did not achieve complete symptom control. Secondly, this study identified that self-management self-efficacy significantly reduced at six months. This area would benefit from further research to establish why self-efficacy reduced at six months, and subsequently, to identify areas for intervention. These findings perhaps provide support to the development of an intervention study to improve quality of life, self-management self-efficacy and improve patients' symptom management. The findings from the individual case studies may provide useful insight to indicate the content of such an intervention study.

6. RESULTS – EMA Adapted/N-of-1

6.1 Short chapter abstract

Background

Most healthcare research and the findings from the prospective longitudinal study (chapter 5) were restricted to aggregate group level effects, introduced retrospective memory recall bias, and overlooked the importance of *within-person* experience. To overcome the limitations of aggregate group level effects and to build upon the findings in chapter 5, a sensible approach to advance this field further was to use case-based time series studies. The EMA adapted/N-of-1 case series was used test the mechanism effects between coping and social support on emotional outcome, within individuals over time. The EMA adapted/N-of-1 case series was also used to assess the self-management behaviours and social supportive experiences of men affected by prostate cancer over time. This is the first study that has assessed the feasibility of real time data collection methods in prostate cancer survivors.

Aim

To test the mechanism effects between coping and social support on emotional outcome, within individuals over time. In addition, the EMA adapted/N-of-1 case series was used to assess the self-management behaviours and social supportive experiences of men affected by prostate cancer over time.

Methods

A Research Steering Group informed the development of the EMA adapted/N-of-1 case series. Twelve EMA adapted/N-of-1 studies were purposively sampled based upon the following criteria: cancer stage, level of social support, marital status and existing co-morbidity. Data collection was managed by using the Dell Axim X51 and Pocket Interview software. Data collection commenced within several weeks following primary treatment. Self-reports were collected for 31 days prompted by an audio alarm three times per day (a total of 93 data entries) for each of the twelve case studies. The structure of the diary consisted of a standard entry, end-of-day entry and incident entry. Data were analysed using traditional exploratory analysis, autocorrelograms, pre-whitening of variables, correlation and multiple regression. Data were analysed using SPSS version 17.0.

Results

Two participants had response rates >80% and nine participants had response rates >90%, and one man's data was lost due to a technical problem. Men used social support as a form of self-management behaviour among many other strategies to improve urinary, bowel and sexual dysfunction, but often with little relief. A common theme across all of the 11 case studies was that men very frequently experienced a range of symptoms for which they did not perform any self-management. Testing the propositions of social support theory "within individuals" over time demonstrated different results for main, moderation and mediating pathways that linked coping and social support to emotional outcome. For two men, negative effects of social support were identified and this finding suggests that not all support provisions are helpful. For six men the propositions of social support theory did not hold with person design.

Conclusion

This unique study has identified the limitations of aggregate group level effects because this study has demonstrated that one size does not fit all. Real time data collection moves far beyond traditional retrospective evaluations, enabling a much clearer understanding of the patient experience throughout the cancer journey. This study has demonstrated the feasibility and acceptability of e-health technologies for men affected by prostate cancer. These findings build upon the results in chapter 5 and suggest that men may benefit from a supported self-management intervention study, tailored to the "individual needs" of prostate cancer survivors. However, future research is needed to identify the content of the intervention.

6.2 Introduction

This chapter reports and discusses the findings from the EMA adapted/N-of-1 series. The findings from the prospective longitudinal study (chapter 5) were restricted to aggregate group level effects, and overlooked the importance of *within-person* experience and change over time (see chapter 4, section 4.2). Although the longitudinal survey was prospective it included retrospective questioning and, therefore, retrospective memory recall bias was possible (Shiffman et al., 2008, Stone et al., 2005, Stone et al., 2004, Stone et al., 2003a,

Stone and Shiffman, 2002). Consequently, the real-life validity of the data presented from the prospective longitudinal study is unknown (Jones and Johnston, 2011). To overcome the limitations of aggregate group level effects and retrospective memory recall bias, a sensible approach to advance the field further was to use N-of-1 time series studies. N-of-1 time series studies (Molenaar, 2004) can form the *pre-clinical and theoretical modelling* stages of the Medical Research Council's framework for complex interventions (Craig et al., 2008). Applying theoretical constructs to individuals will enrich and expand empirical reach to tailor interventions at the individual level of change (Borckardt et al., 2008) and can reduce retrospective memory recall bias.

The EMA adapted/N-of-1 case series was used to test the propositions of social support theory (Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984) within *individuals.* Empirically testing theoretical models within individuals can identify the potential for future interventions that are theoretically driven and appropriately targeted. In relation to the research questions, this EMA adapted/N-of-1 series was used to test the mechanism effect between coping and social support on emotional outcome, within individuals over time. In addition, the EMA adapted/N-of-1 series was used to assess the self-management behaviours and the social supportive experiences of men affected by prostate cancer over time. This is the first study that has assessed the feasibility of real time data collection methods in prostate cancer survivors. It was important to identify any potential bias in agreement to complete the electronic diary and to establish questionnaire response rates. This case series has provided a unique insight into the individual experiences of eleven men with different clinical characteristics, demographic backgrounds, and level of social support, which allowed for some replication.

6.3 Research questions

The series of EMA adapted/N-of-1 studies addressed the following questions:

In prostate cancer survivors:
1a. What patient characteristics influence agreement to complete the EMA adapted/N-of-1 data?

1b. What are the response rates of participants filling out a diary over several weeks?

2a. What are the daily self-management behaviours in real time and do they change over time?

2b. What are the daily social supportive experiences in real time and do they change over time?

2c. Do social supportive experiences have a main effect, or do they moderate/mediate the relationship between coping and mood in real time?

6.4 Methods

A Research Steering Group informed the development of the EMA adapted/N-of-1 case series. Twelve EMA adapted/N-of-1 studies were purposively sampled based upon the following criteria: cancer stage, level of social support, marital status and existing co-morbidity. Data collection was managed by using the Dell Axim X51 and Pocket Interview software. Data collection commenced within several weeks following primary treatment. Self-reports were collected for 31 days prompted by an audio alarm three times per day (a total of 93 data entries) for each of the twelve case studies. The structure of the diary consisted of a standard entry, end-of-day entry and incident entry. The content of the diary questions was mapped to the constructs of the questionnaires and the items were informed by the literature and comment from clinicians and prostate cancer patients (see appendix 4.14 for diary schedule and screenshot examples of the PDA). Most question items were presented on the PDA using a visual analogue scale (VAS) from 0-100 scale. The question items presented on the diary consisted of a 'standard diary entry' (completed 3 times per day), an 'end-of-day entry' (completed once per day, immediately following the third standard entry each day), and an 'incident entry' that could be completed at any time throughout the 1-month period (see table 6.1 for an overview of the measurements used in the diary).

Table 6.1 An overview of the measurements used in the diary

Enquiry	Subscale and variables	Number of items	Data presented in this chapter
Standard Entry (3 times per day, for a total of 1	**Negative affect*** How do you feel just now? (0-100) Nervous, Frustrated, Sad, Angry, Stressed, Tired	6	Yes
	Positive affect* How do you feel just now? (0-100)	3	Yes

month (n=93)	Alert, Happy, Energetic **Positive coping** Please rate each of the following statements which describes how you have coped in the past few hours with your self-care? (0-100) I tried to keep a positive attitude **Negative coping*** Please rate each of the following statements which describes how you have coped in the past few hours with your self-care? (0-100) I felt like giving up, I felt problems with my health prevented me from planning ahead, I felt that nothing I can do will make a difference, I tried not to think about it **Perceived social support*** Do you have enough available support from people around you? (0-100) Financial, Emotional, Practical, Informational **Received social support*** How much support have you received in the past few hours? (0-100) Financial, Emotional, Practical, Informational **Sought social support** Have you sought out social support in the past few hours? (yes/no) **Self-management demand** How demanding has self-care been for you? (0-100) **Self-management control** How much control have you had over your self-care? (0-100) **Self-management self-efficacy*** I can always manage to complete self-care tasks that are difficult for me (0-100), I am confident in carrying out my self-care activities (0-100)	1 4 4 4 1 1 1 2	Yes Yes Yes Yes Yes Yes Yes Yes
End of Day Entry (Once per day, for a total of 1 month (n=31)	**Urinary self-management behaviours** What types of self-care have you used today to help with your water works (urine)? (tick box) None, Took medication, Found out information, Increased fluid intake, Used pads, Used catheters, Used urine sheaths Pelvic floor exercises, Avoided heavy lifting, Kept a toileting diary, Avoided caffeine based drinks, Shared my feelings, Other (free text) **Bowel self-management behaviours** What types of self-care have you used today to help with your bowels? (tick box) None, Took medication, Increased fluid intake, Changed diet, Used pads, Did pelvic floor exercises, Kept a toileting diary, Found out information, Comfort (hot water bottle), shared my feelings, Other (free text) **Sexual function self-management behaviours** What types of self-care have you used today to help with your sexual function? (tick box) None, Took medication, Found out information, Tried to lose weight (if overweight), Limited alcohol intake, Stopped smoking (if smoker), Used a penis pump, Took exercise, Found ways to reduce stress, Shared my feelings, Other (free text)	13 11 11	Yes Yes Yes
Enquiry	**Subscale and variables**	**Number of items**	**Data presented in this chapter**
End of Day Entry (Once per day, for a total of 1 month (n=31)	**Urinary self-management relief** Generally, did your self-care actions relieve the problem? (0-100) **Bowel self-management relief** Generally, did your self-care actions relieve the problem? (0-100) **Sexual-function self-management relief** Generally, did your self-care actions relieve the problem? (0-100) **Overall, self-care self-efficacy*** Overall today I feel that: (0-100) I can always manage to complete self-care activities that	1 1 1 2	Yes Yes Yes Yes

	are difficult for me, I am confident in carrying out my self-care activities		
	Symptoms To what extent have you experienced the following symptoms today? (0-100) Blood in the urine, Constipation, Diarrhoea, Nausea, Pain, Tiredness, Unable to sleep, Urgency to pass urine, Urinary frequency (day and night), Vomiting, Impotence, Other symptom (free text)	14	Yes
	Most demanding self-care What was your most demanding self-care task that you had to do today? (free text)	1	Yes
	Satisfaction with social support* How satisfied were you with your support today? (0-100) Financial, Emotional, Information, Practice	4	Yes
	Thoughts and feelings Were you able to discuss your thoughts and feelings today? Did you want to discuss your thoughts and feelings today? (0-100)	2	Yes
	Quality of Life How would you rate your quality of life today? (0-100	1	Yes
Incident Entry (Event contingent (any time throughout 1-month period)	**Negative affect*** How do you feel just now? (0-100) Nervous, Frustrated, Sad, Angry, Stressed, Tired	6	Yes
	Positive affect* How do you feel just now? (0-100) Alert, Happy, Energetic	3	Yes
	Experience Please describe your experience that was very demanding for you? (free text)	1	Yes
	Positive coping Please rate each of the following statements which describes how you have coped with this experience?(0-100) I tried to keep a positive attitude	1	Yes
	Negative coping* Please rate each of the following statements which describes how you have coped with this experience?(0-100) I felt like giving up, I felt problems with my health prevented me from planning ahead, I felt that nothing I can do will make a difference, I tried not to think about it	4	Yes
	Sought support Did you seek support to help with this experience? (Yes/no)	1	Yes
	Perceived social support Did you have enough support available from people around you? Was that enough support? (0-100)	2	Yes

- Summary score used in the analysis.

This study measured satisfaction with social support over time, and the interpretation of a "low score" in satisfaction with social support, should not be interpreted as "dissatisfaction" with social support, because this construct was not explicitly measured. The symptoms that were assessed in the diary included the following: blood in the urine, constipation, diarrhoea, nausea, pain, tiredness, unable to sleep, urgency to pass urine, urinary frequency (day and night), vomiting, impotence, and other symptoms (free text). These particular symptoms were assessed because of the clinical heterogeneity (various treatments and cancer stages) across the case studies, and the length of the diary entry, such that, the diary entry was not too long for the participants to complete. The symptoms

chosen were informed by the EORTC C30 and PR25, discussions with clinicians, and men with prostate cancer. A number of symptoms were not explicitly assessed, and included the following: pain/proctitis, leakage of stools, hot flushes, painful nipples or breasts, blood in stools, oedema, bloated abdomen, weight loss, weight gain; but the participants were given an opportunity to share these symptoms by "free text" in the diary entry. It is important to acknowledge that the participants may not have used the "free text" option to report additional symptoms; therefore, the symptoms experienced could be unrelated to the self-management behaviours reported. For example, constipation and diarrhoea were explicitly assessed, but not blood in stools, or proctitis, and therefore; the reported behaviours could be related to other symptoms for which no data was captured. Each of the self-management behaviours were chosen through discussions with clinicians, men with prostate cancer and from the literature reviewed in chapter 3. The researcher considered it to be very important to include a response option for "other" (free text option) self-management behaviours which captured additional self-management that the standard response would have missed.

For a detailed overview of the methods used in the series of EMA adapted/N-of-1 studies (chapter 4, section 4.7).

6.4.1 Statistical analysis

The diary data were transferred from Microsoft Access into SPSS version 17.0. The standard entry variables were examined for autocorrelation using autocorrelograms (Tabachnick and Fidell, 2007) produced in SPSS. Variables that displayed autocorrelation were pre-whitened based on guidance from previous studies (Borckardt et al., 2008, Crane et al., 2003, Cromwell et al., 1994). Pre-whitened variables were examined using autocorrelograms to check that the autocorrelation was successfully removed from the variable. When variables did not meet the assumptions for a particular analysis, transformations were performed (Tabachnick and Fidell, 2007). Transformations of the variables are detailed individually within each case study. Statistical analysis was performed using parametric tests (paired t-tests, bivariate correlations and hierarchical multiple regression) and non-parametric tests (Chi^2 tests). Hierarchical multiple regression analyses were performed to test for main, moderation and mediation

effects of coping (positive and negative) and social support (perceived and received) variables on emotional outcome, (see chapter 4, section 4.7.7) for a description of moderation and mediation analysis. Prior to each regression analysis, the evaluation of the assumptions were checked (see appendix 6.1 for the heuristics used in the statistical analysis for EMA adapted/N-of-1 data).

6.5 Results

6.5.1 Characteristics of the participants

Seventy-four men consented to take part in the prospective longitudinal study and of those 74 men, 62 (83.8%) consented to take part in the EMA adapted/N-of-1 study. A sampling framework (see chapter 4, section 4.7.6 for sampling framework) was applied to the 62 men who agreed to take part in the EMA adapted/N-of-study (see figure 6.1 for an overview).

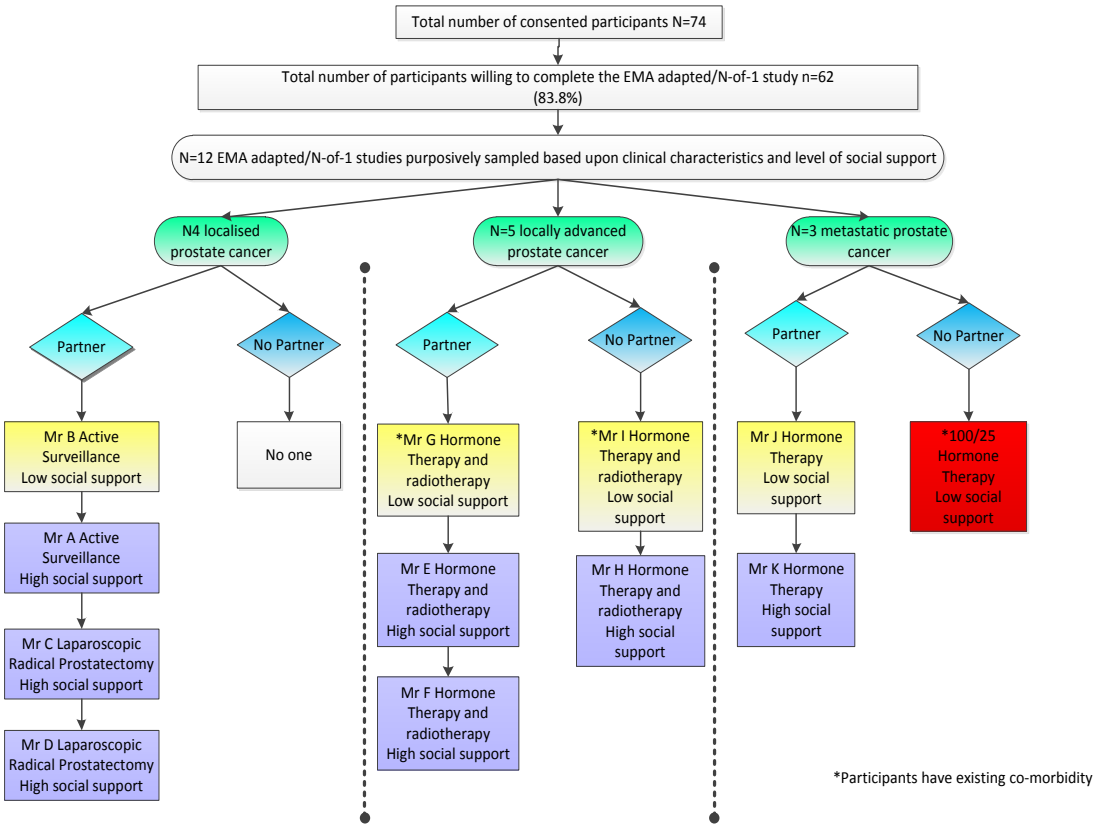


Figure 6.1 Overview of the participants who completed the EMA adapted/N-of-1

Unfortunately, participant 100/25's (highlighted in red, in figure 6.1) data were not recorded on the PDA throughout his one-month period of data collection and, therefore, could not be included. The participant verbally expressed good

compliance with the diary data collection schedule, but he did not "tap" the "finish button" at the end of each diary entry. As a limitation of the diary software, the self-report data were not recorded and were unable to be retrieved, as informed by the software programme developer. No other participants met the sampling framework criteria (see chapter 4, section 4.7.6 for sampling framework). Eleven men completed the EMA adapted/N-of-1 data entry within their 6 months of participation in the study. The specific timings for each treatment modality are detailed in chapter 4, section 4.7.6.

Research questions

6.5.2 Which patient characteristics influence agreement to complete real time data collection of the N-of-1 single-case data?

Comparisons were performed with demographic (age, education, employment, socio-economic, marital) and clinical (cancer stage, cancer treatment, PSA, Gleason score and co-morbidity) variables to identify differences between those consenting for the diary (n=62, 83.8%) and those who did not consent (n=12, 16.2%) (see table 6.2). This analysis was undertaken by independent sample t-tests and Chi² test.

Table 6.2 Comparisons of clinical and demographic variables between those who consented to complete the EMA adapted/N-of-1 data and those who did not consented to the EMA adapted/N-of-1 data collection

Variables	**Consented to complete the electronic diary (n=62, 83.8%)**	**Did not consent to completing the electronic diary (n=12, 16.2%)**	Comparisons
Age (years) at study consent	69.7 (SD 7.8)	72.0 (SD 9.4)	t(72)=0.914, p=0.361
Education			
High school	9.7% (n=6)	8.3% (n=1)	The assumption for 'minimum expected cell frequency' was not met for the Chi² -test.
Further education	22.6% (n=14)	8.3% (n=1)	
Higher education	22.6% (n=14)	33.3% (n=4)	
Trade qualification	40.3%(n=25)	16.8% (n=2)	
No qualifications	4.8% (n=3)	33.3% (n=4)	
School leaving age (years)	16.2 (SD 1.4)	15.9 (SD 1.5)	t(72)=-1.232, p=0.221
Employment			The Chi²-test was performed with employed and retired categories only, because the participants in the unemployed categories (n=2) were very small for the entire study sample. χ^2 (1)=0.626, p=0.431 Fisher's Exact Test p=0.502, (2-tailed).
Unemployed	3.2% (n2)	0% (n0)	
Employed	29.0% (n18)	41.7% (n5)	
Retired	67.7% (n42)	58.3% (n7)	
Socio-economic (SIMD)			
1 most deprived	3.2% (n2)	16.7% (n2)	The assumption for 'minimum expected cell frequency' was not met for the Chi²-test.
2	6.5% (n4)	16.7% (n2)	
3	16.1% (n10)	25.0% (n3)	

4 5 Least deprived	48.4% (n30) 25.8% (n16)	25.0% (n3) 16.7% (n2)	
Martial Partner No partner	 80.6% (n50) 19.4% (n12)	 83.3% (n10) 16.7% (n2)	χ^2 (1)=0.047, p=0.833. Fisher's Exact Test p=1.0 (2-tailed)
Cancer stage Localised Locally advanced Metastatic	 43.5% (n27) 50.0% (n31) 6.5% (n4)	 41.7% (n5) 16.7% (n2) 41.7% (n5)	χ^2 (2)=12.765, p=0.002, Cramer's V statistic =0.415, p=0.002.**
Cancer treatment Watchful waiting RRP LRP EBRT Hormone therapy Active surveillance Hormone therapy and EBRT	 4.8% (n3) 1.6% (n1) 11.3% (n7) 9.7% (n6) 14.5% (n9) 11.3% (n7) 46.8% (n29)	 0% (n0) 0% (n0) 8.3% (n1) 0% (n0) 41.7% (n5) 16.7% (n2) 33.3% (n4)	The assumption for 'minimum expected cell frequency' was not met for the Chi²-test.
PSA	26.1 (SD 31.8)	56.6 (SD 86.6)	t(11.6)=1.205, p= 0.253
Gleason Low grade (2-4) Intermediate grade (5-7) High grade (8-10)	 0 % (n0) 74.2% (n46) 25.8% (n16)	 0% (n0) 58.3% (n7) 41.7% (n5)	χ^2 (1)=1.244, p=0.262. Fisher's Exact Test p=0.303, 2-tailed)
Existing co-morbidity (yes)	*71.0% (n44)*	*58.3% (n7)*	χ^2 (1)=0.749, p=0.384 Fisher's Exact Test p=0.498, (2-tailed)

*p<0.05, **p<0.01

The independent samples t-tests identified no significant differences between those consenting to complete the diary and those who did not for the following variables: age, school leaving age and PSA level. No significant differences were found between the groups for employment, marital status, Gleason score and pre-existing co-morbidity (Fisher's exact test all P>0.05, 2-tailed). Assumptions for the Chi²-test were not met for socio-economic, education and treatment and therefore, it was not possible to explore the relationships among these variables. A significant association was found between cancer stage and whether or not participants consented to complete the diary: χ^2 (2)=12.765, p=0.002, Cramer's V statistic =0.415, p=0.002. Of those men with metastatic disease, significantly fewer than expected were willing to participate in the diary study. However, caution is taken in the interpretation of this result due to the small number of study participants.

6.5.3 What are the response rates of participants filling a diary over several weeks?

The response rates for the diary data collection were very high; see table 6.3 for an overview of the response rates. Two participants had response rates greater than 80%, and nine participants demonstrated a response rate greater than 90%.

Table 6.3 Electronic diary response rates

Participant and social support	Response rate	Cancer stage and treatment	Co-morbidity	Age	Education-highest qualification	Employment	Socio-economic (SIMD 1 most deprived – 5 least deprived)	Diary Schedule
Mr A Partner High support	94.6%	Localised prostate cancer AS	No	73	HNC	Retired	4	10am, 4pm, 10pm
Mr B Partner Low support	90.3%	Localised prostate cancer AS	No	61	BA	Employed	4	10am, 4pm, 10pm
Mr C Partner High support	87%	Localised prostate cancer LRP	No	51	No qualification	Employed	2	8am, 2pm, 8pm
Mr D Partner High support	97.7%	Localised prostate cancer LRP	No	59	Trade qualification	Retired	5	10am, 4pm, 10pm
Mr E Partner High support	97.9%	Locally advanced prostate cancer HT and EBRT	No	65	Trade qualification	Retired	4	10am, 4pm, 10pm
Mr F Partner High support	90.3%	Locally advanced prostate cancer HT and EBRT	No	57	Trade qualification	Employed	1	10am, 4pm, 10pm
Mr G Partner Low support	97.9%	Locally advanced prostate cancer HT and EBRT	Yes Asthma Hypertension Depression	64	HND	Retired	4	10am, 4pm, 10pm
Mr H No partner High support	97.8%	Locally advanced prostate cancer HT and EBRT	No	73	Trade qualification	Employed	4	9am, 3pm, 9pm
Mr I No partner Low support	81.7%	Locally advanced prostate cancer HT and EBRT	Yes Asthma Hypertension	73	Post graduate HND	Retired	4	9am, 3pm, 9pm
Mr J Partner Low support	94.6%	Metastatic disease HT	No	73	A levels	Retired	3	9am, 3pm, 9pm
Mr K Partner High support	91.3%	Metastatic disease HT	No	72	Trade qualification	Retired	5	10am, 4pm, 10pm

AS (Active surveillance), LRP (Laparoscopic radical prostatectomy), HT (Hormone therapy), EBRT (External beam radiotherapy)

6.5.4 What are the daily self-management behaviours in real time and do they change over time?

The self-management behaviours (for all the 11 men) were mainly related to three areas: urinary, bowel and sexual dysfunction, but men also experienced other problems for which they performed self-management. Table 6.4 provides a brief summary of the symptoms experienced and the self-management actions performed to relieve/prevent the symptoms across the eleven case studies.

Table 6.4 Brief summary of symptoms experienced and the self-management actions performed to relieve the symptoms across the eleven case studies

	Symptoms	**Self-management behaviours**
Urinary dysfunction	Urinary urgency Urinary incontinence Urinary frequency (during day) Urinary frequency (during the night) Blood in the urine	Took medication Found out information Increased fluid intake Used pads Used catheter sheaths Avoided heavy lifting Reduced caffeine intake Shared thoughts and feelings Drank cranberry juice Reduced alcohol Kept a toileting diary Washed incontinence pads Mind over matter strategies
Bowel dysfunction	Constipation Diarrhoea Rectal pain Bleeding from anus	Took medication Took a high fibre diet Took califig/fybogel Applied anusol Changed fluid intake Used pads Shared my thoughts and feelings Changed diet Kept a toileting diary Took exercise
Sexual dysfunction	Impotence	Found out information Shared thoughts and feelings Took medication Limited alcohol intake Reduced stress
Other	Ankle oedema	Went for a walk Took furosamide pill Elevated feet when sitting
Other	Infected surgical wound	Dressed wound Sought help from nurse and doctor Changed and emptied wound drainage bag Took antibiotic tablets
Other	Poor sleeping patterns/problems with relaxation	Increased amitriptyline dosage Took a large whisky before bed
Other	Morning sickness	Took anti-sickness tablets
Other	Radiation burns to abdomen and penis	Applied gel given from doctor Applied savlon and aqueous cream Wiped tip of penis after urinating

The number of days that men performed self-management to relieve urinary, bowel and sexual dysfunction varied across the eleven single-case studies (see table 6.5). Men diagnosed with localised and locally advanced prostate cancer performed self-

management for urinary, bowel, and sexual dysfunction over time. However, the men (Mr J and Mr K) diagnosed with metastatic cancer did not report any self-management behaviours over the one-month period of data collection.

Table 6.5 The number of days that self-management was performed over 1 month to relieve urinary, bowel and sexual dysfunction across the eleven case studies.

	Social support	**Clinical details**	**Self-management of urinary symptoms**	**Self-management of bowel symptoms**	**Self-management of sexual function symptoms**
Mr A	Partner high support	Localised cancer AS	5 days	None	None
Mr B	Partner low support	Localised cancer AS	29 days	None	None
Mr C	Partner high support	Localised cancer LRP	31 days	8 days	1 day
Mr D	Partner high support	Localised cancer LRP	30 days	None	None
Mr E	Partner high support	Locally advanced cancer HT and EBRT	None	3 days	None
Mr F	Partner high support	Locally advanced cancer HT and EBRT	25 days	3 days	None
Mr G	Partner low support	Locally advanced cancer HT and EBRT	31 days	31 days	None
Mr H	No partner high support	Locally advanced cancer HT and EBRT	12 days	13 days	11 days
Mr I	No partner low support	Locally advanced cancer HT and EBRT	30 days	30 days	1 day
Mr J	Partner low support	Metastatic cancer HT	None	None	None
Mr K	Partner high support	Metastatic cancer HT	None	None	None

AS (Active surveillance), LRP (Laparoscopic radical prostatectomy), HT (Hormone therapy), EBRT (External beam radiotherapy)

To understand the individual man's experience of self-management and change over time, the following section identifies the self-management behaviours, symptoms

experienced, and the self-management relief of symptoms over time, within the context of each single-case study.

Mr A (localised cancer- active surveillance)

Mr A was a 73-year-old married man who reported high social support. He performed urinary self-management on 5 days and reported good relief from these as illustrated from the blue line in figure 6.2. The actual self-management behaviours were not reported. Urinary symptoms were not frequently experienced over time as illustrated in Figure 6.2. No further self-management behaviours were performed.

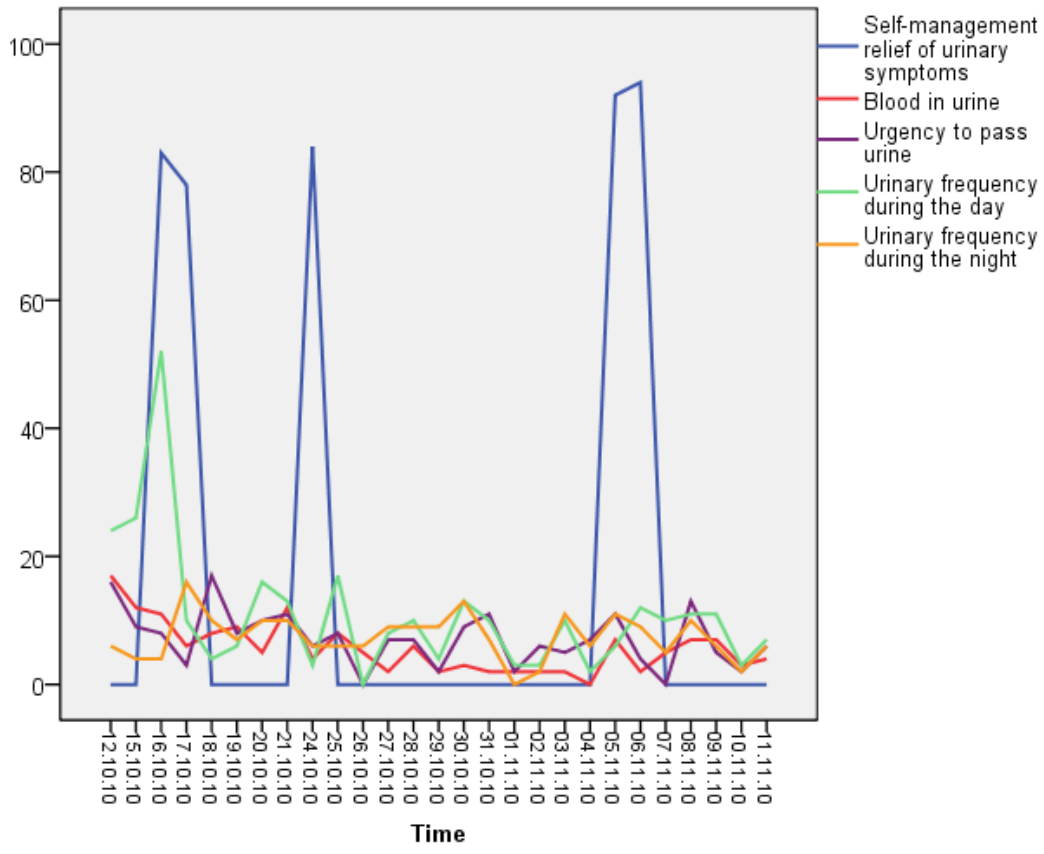


Figure 6.2 Mr A: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr B (localised cancer- active surveillance)

Mr B experienced urinary frequency and urinary urgency every day (see the green, orange and purple lines in figure 6.3) and he took medication daily as his only self-management behaviour. No trend of symptom relief was observed over time (see blue line in figure 6.3), except for on the 07.12.10, whereby Mr B indicated improved urinary symptoms. No further self-management was performed.

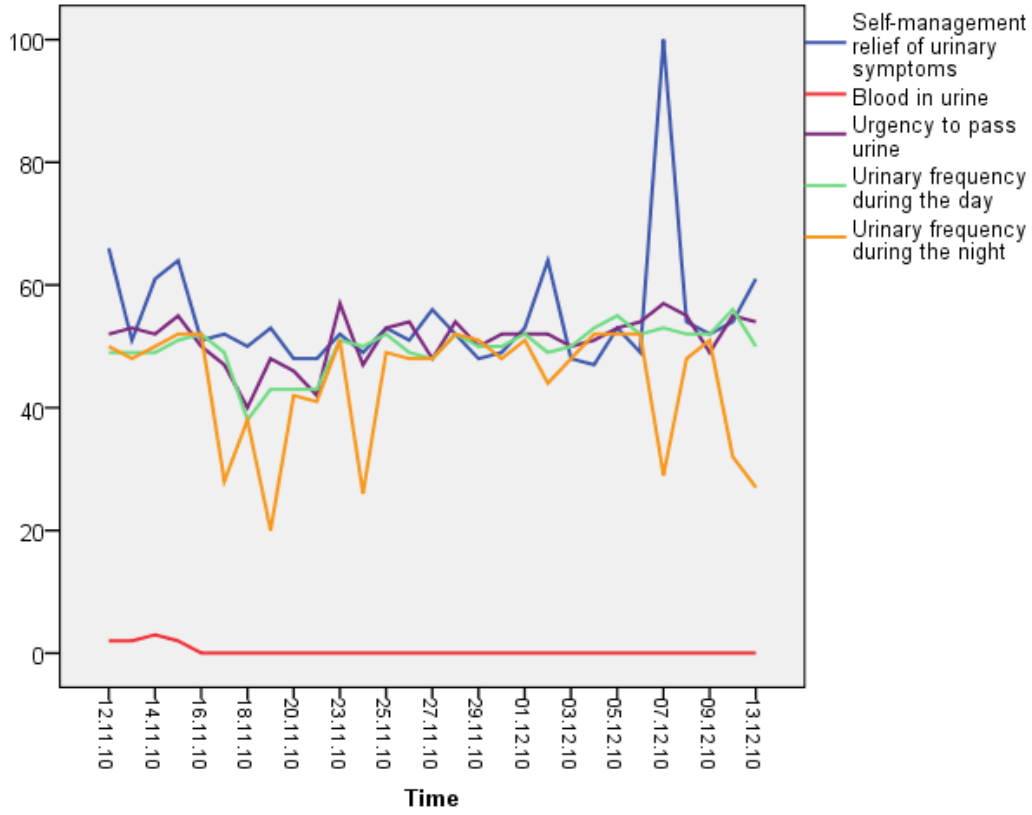


Figure 6.3 Mr B: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr A and Mr B were both diagnosed with localised prostate cancer and were under active surveillance, but both men displayed different urinary symptoms over time. Mr B experienced more frequent urinary symptoms over time compared to Mr A. The two men did not have pre-existing health problems and had no previous prostate cancer treatment to account for the different urinary symptom profiles over time. It

is possible that physiologically, Mr B's prostate cancer tumour was closer to his lower urinary tract to account for his urinary symptoms (Krupski et al., 2003), but this will remain unknown. Both men were married, but Mr A reported high social support whereas Mr B had low social support. It may be that Mr B was not aware of available resources to help with his self-management of his urinary symptoms and this has been reported elsewhere (Ream et al., 2008), but ultimately, this will remain unknown.

Mr C (Localised cancer – Laparoscopic radical prostatectomy)

Mr C was a 51-year-old married man who reported high social support. Nine self-management behaviours were performed to relieve urinary symptoms (see figure 6.4 for self-management strategies). Urinary symptoms were frequently experienced and no visible trend of relief from self-management strategies was observed over time (see figure 6.5), but on 26.02.10, self-management appears to be effective in relieving urinary symptoms. One explanation to account for improved symptoms over time could be due to successful self-management behaviours, but recognising that urinary symptoms may have naturally improved over time as part of post-surgery recovery (Lee et al., 2001). Mr A and Mr B both had localised prostate cancer but the frequency of their urinary symptoms over time remained fairly stable. Whereas Mr C, who had invasive surgery for his localised cancer and the frequency of his urinary symptoms were more erratic, shows a trend of symptom improvement over time (see orange, green and purple lines in figure 6.5 for urinary symptoms).

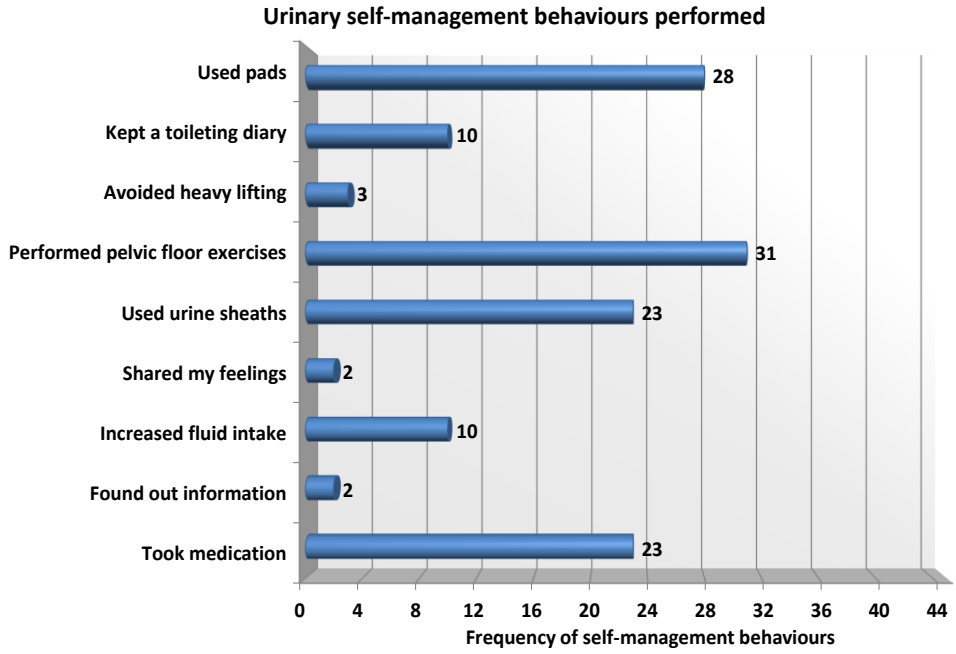


Figure 6.4 Mr C: Distribution of urinary self-management behaviours

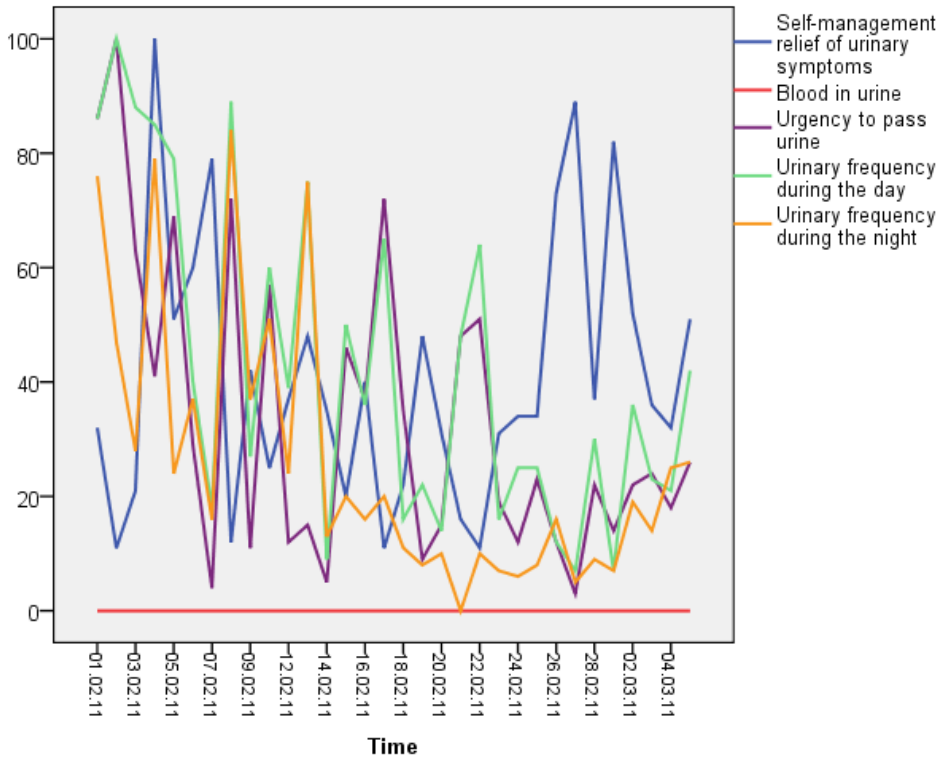


Figure 6.5 Mr C: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Bowel symptoms were experienced less frequently and constipation was the only reported symptom over time (see green line in figure 6.6). Mr C took medication as his only bowel self-management action on eight days and reported good relief from this (see blue line in figure 6.6).

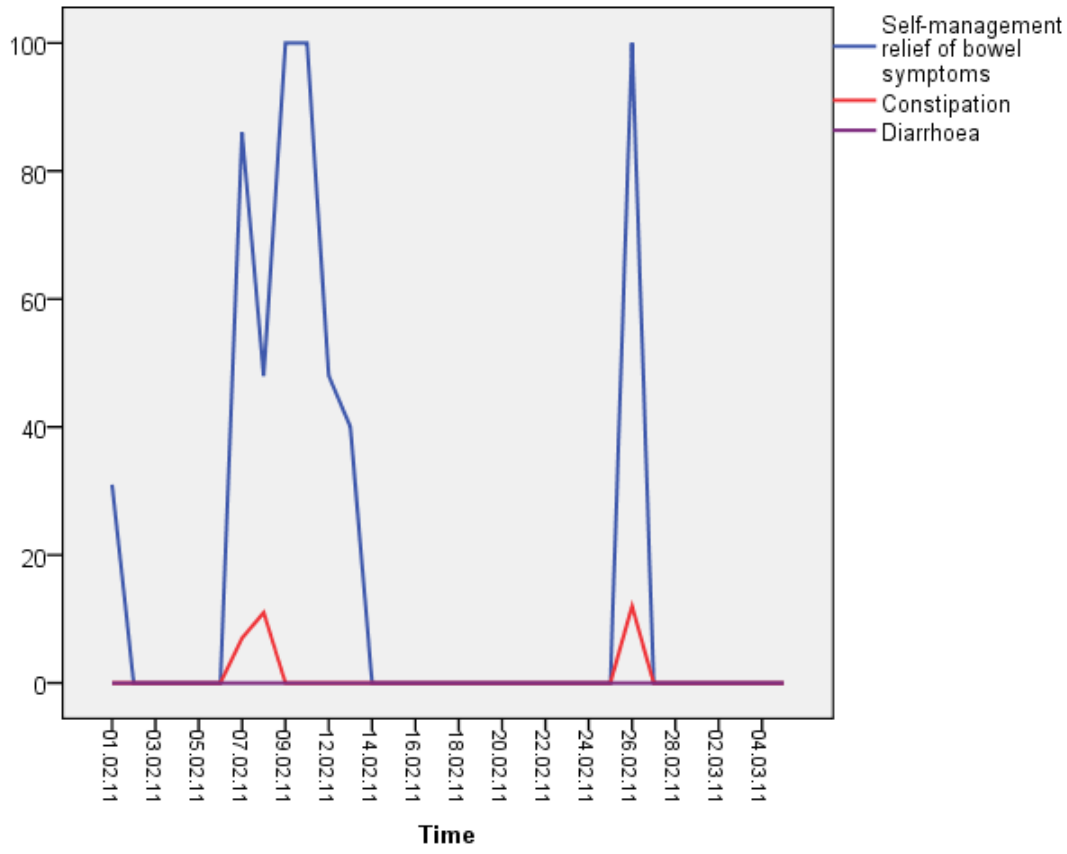


Figure 6.6 Mr C: Frequency of bowel symptoms and self-management relief of bowel symptoms displaying change over time.
The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Impotence was frequently experienced over time (see the red line in figure 6.7). Self-management was performed on one occasion which was sharing his thoughts and feelings and finding out information. He indicated good relief from his behaviours (see blue line in figure 6.7). Mr C experienced impotence every day but only performed self-management on one occasion (25.02.2011). One possible explanation is that reduced sexual function did not bother Mr C at this stage in his recovery (1 month post-surgery) but acknowledging sexual function self-management

may increase over time as he adjusts to living with erectile dysfunction (Nelson et al., 2011, Nelson et al., 2009), but this will remain unknown.

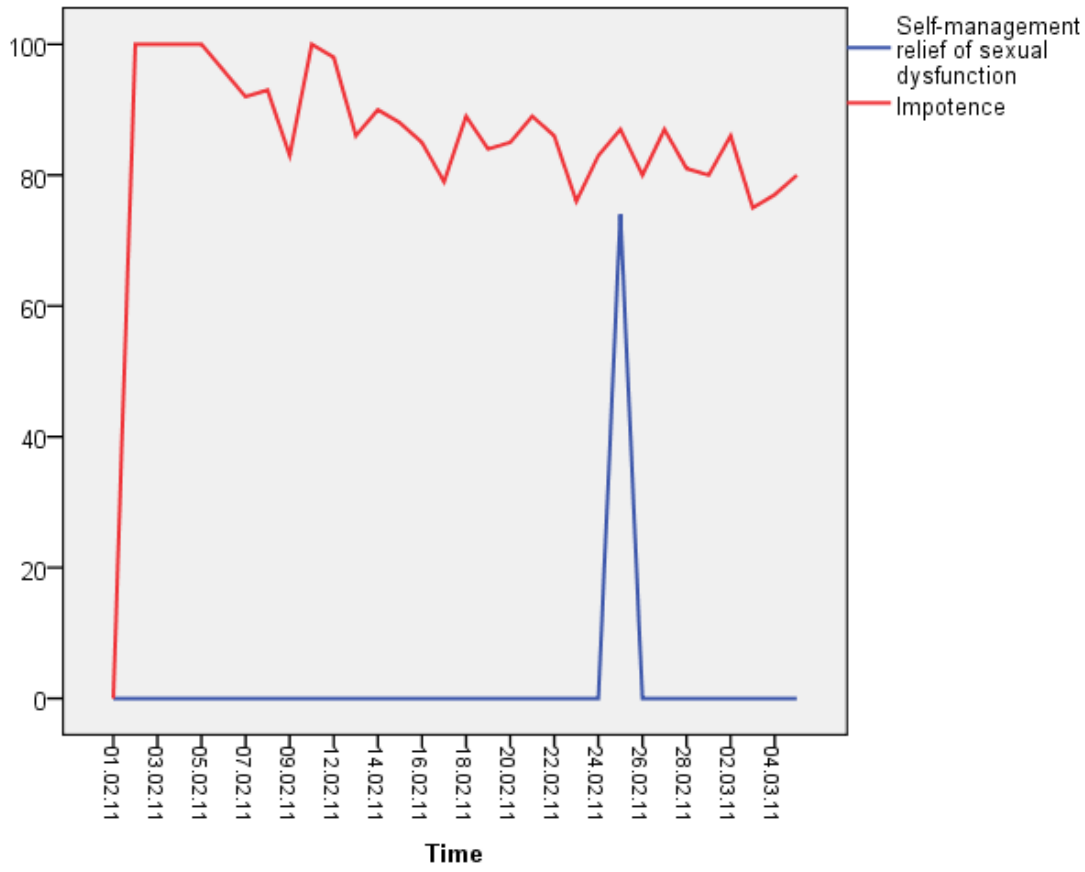


Figure 6.7 Mr C: Frequency of sexual dysfunction and self-management relief of sexual dysfunction displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Self-management was performed for relief of severe rectal pain (see table 6.6). Experiencing rectal pain following radical prostatectomy has been reported elsewhere (Moore and Estey, 1999).

Table 6.6 Mr C: Other symptoms, self-management behaviours and relief

Date	Symptoms	Self-management behaviour	Relief (0-100)
26.02.2011	Severe rectal pain	Tramadol taken	100

A higher score displayed is interpreted as higher relief of self-management

Mr D (Localised cancer – Laparoscopic radical prostatectomy)

Mr D was a 59-year-old man with high social support. Similar to Mr C, Mr D had a radical prostatectomy and performed urinary self-management daily to relieve urinary symptoms. Mr D performed two self-management behaviours (took medication [on 25 days] and used pads [on 29 days]) and reported good relief from these over time (see the blue line in figure 6.8). A clear visual trend of improved urinary frequency at night (purple line in figure below) is observed over time.

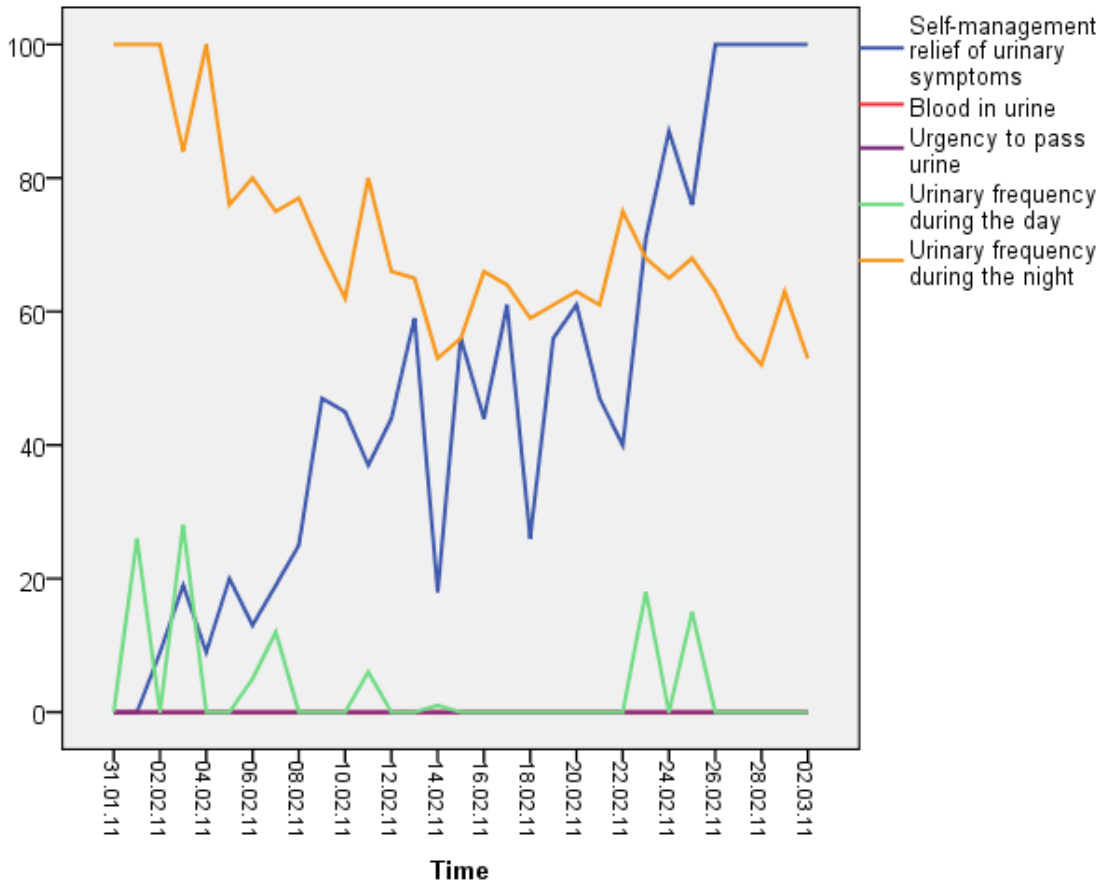


Figure 6.8 Mr D: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr D performed additional self-management for oedema and post-operative wound care (see appendix 6.2 for additional self-management behaviours and relief).

Mr E (locally advanced cancer – hormone therapy and radiotherapy)

Mr E was a married 63-year-old man with high social support. He took medication on three days for diarrhoea (see purple line for diarrhoea in figure 6.9) which was an infrequent symptom experienced. This time series plot indicates good relief from bowel self-management (blue line), and may suggest a lag (time period between two observations) between bowel self-management and diarrhoea. Therefore, Mr E may have performed self-management as prevention rather than a cure. No other self-management behaviours were reported.

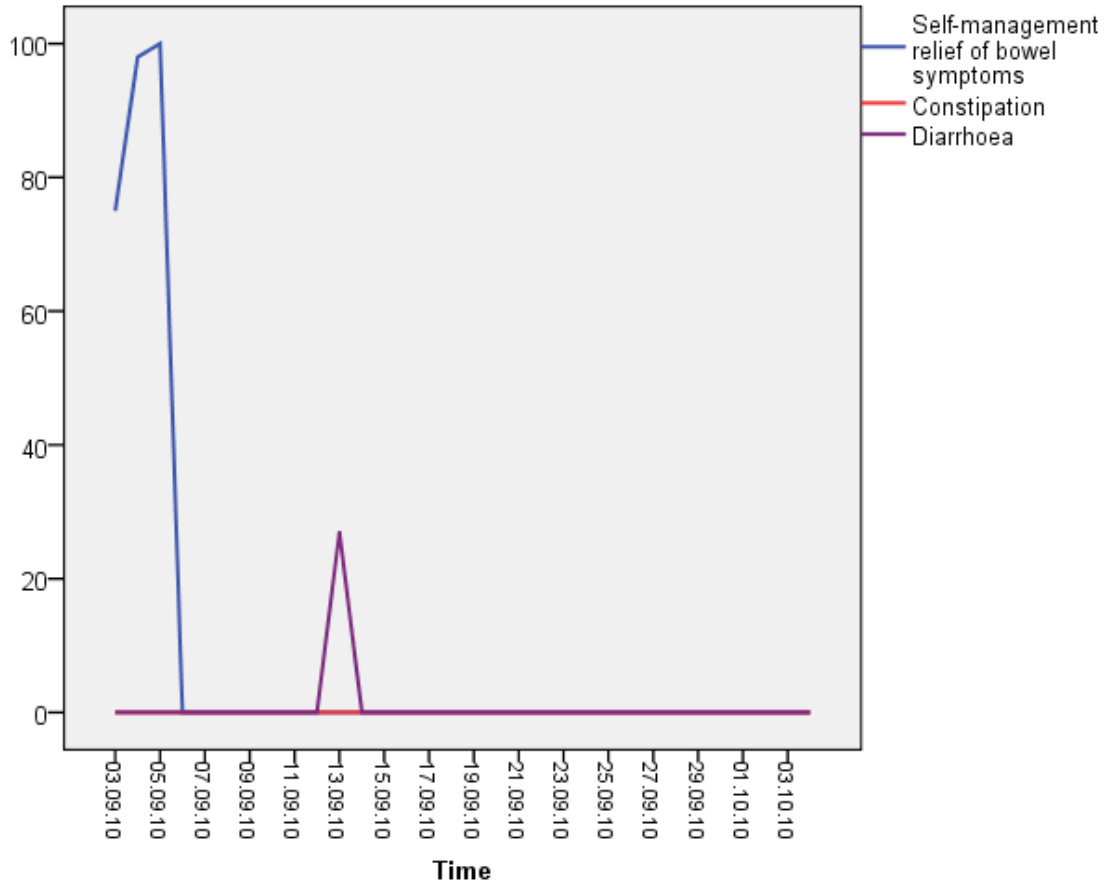


Figure 6.9 Mr E: Frequency of bowel symptoms and self-management relief of bowel symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr F (locally advanced cancer – hormone therapy and radiotherapy)

Mr F was a 57-year-old married man and reported high social support. Mr E and Mr F had the same clinical staging and were treated by the same treatment modality, but Mr F experienced urinary symptoms over time, whereas Mr E did not. This result could be explained by the toxicities caused by radiotherapy (Fonteyne et al., 2009) that were experienced by Mr F and not Mr E. Four urinary self-management actions were performed (see figure 6.10) with good relief from these over time (see blue line in figure 6.11).

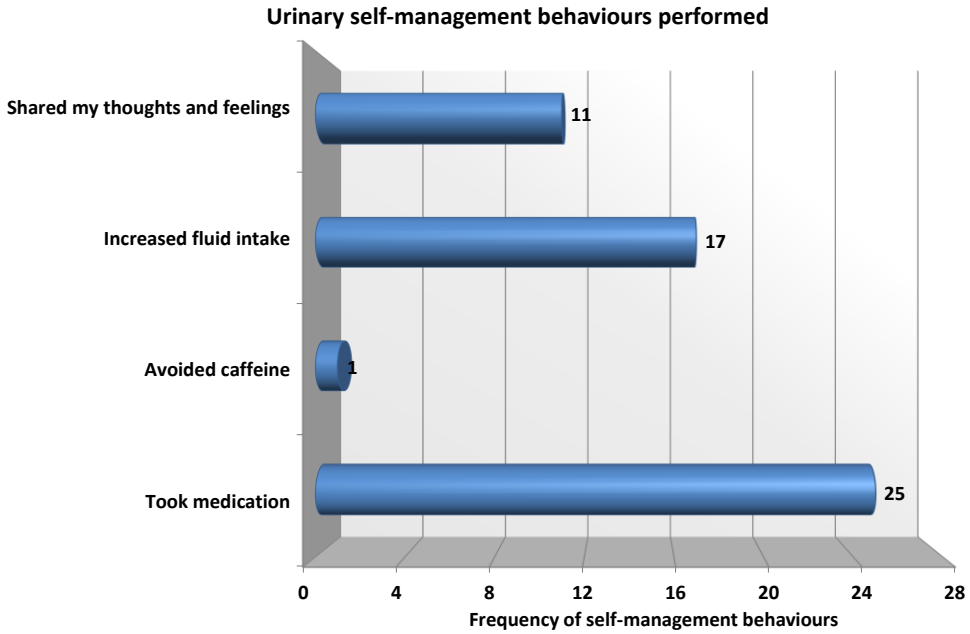


Figure 6.10 Mr F: Distribution of urinary self-management behaviours

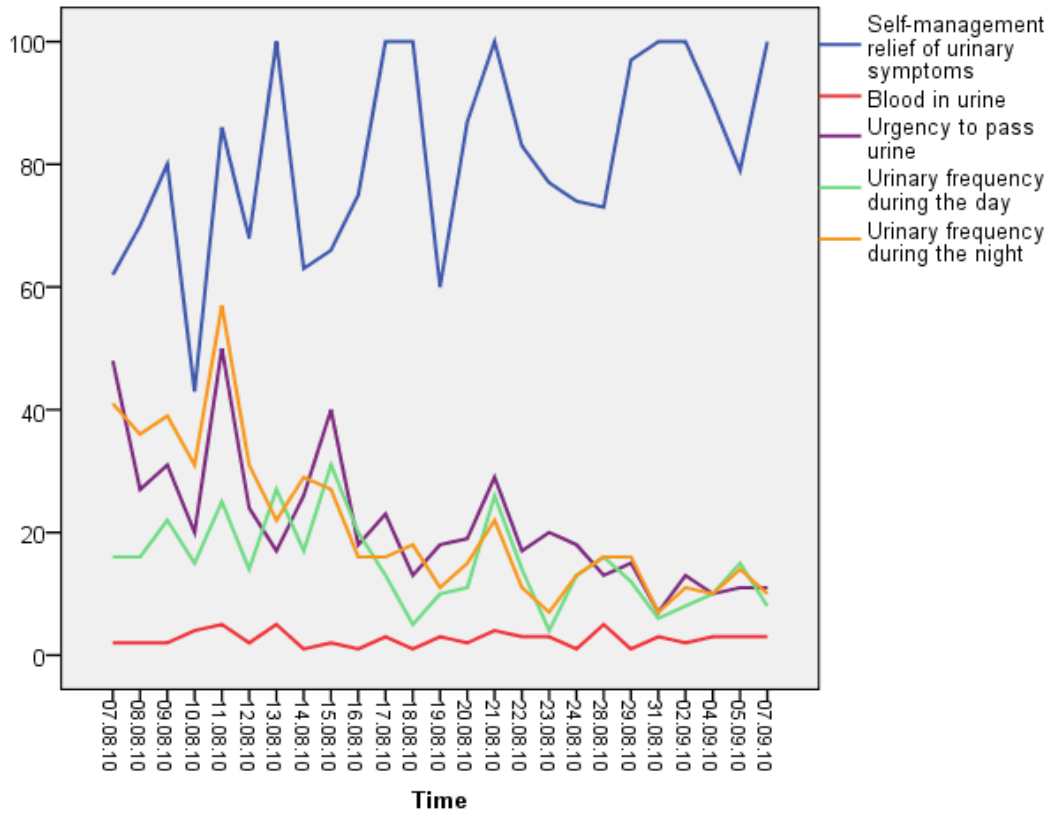


Figure 6.11 Mr F: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Diarrhoea was the most frequent symptom experienced over time (see the purple line in figure 6.12). Mr F took medication and shared his thoughts and feelings on three days and reported good symptom relief from these (see blue line in figure 6.12). Similar to Mr E, Mr F's time series plot indicates a lag (time period between two observations) between self-management and diarrhoea, on the 10.08.10 and the 21.08.12. Mr E may have performed self-management for prevention of bowel symptoms but also for symptom relief. No other self-care behaviours were reported.

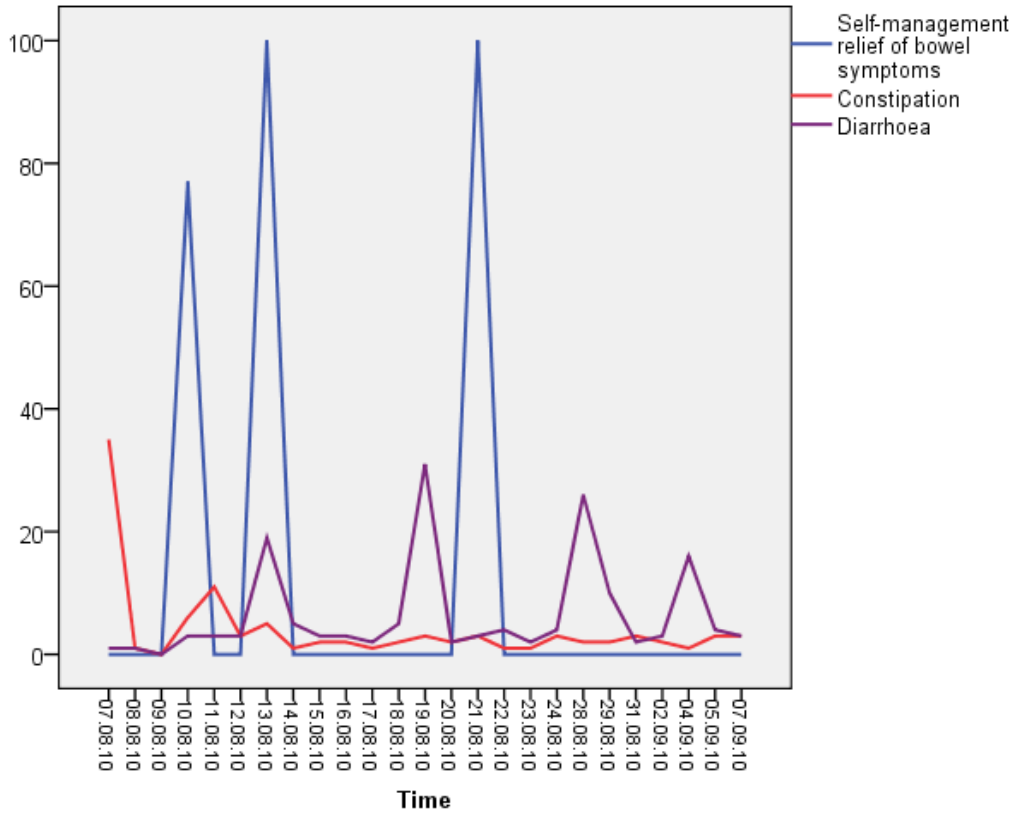


Figure 6.12 Mr F: Frequency of bowel symptoms and self-management relief of bowel symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr G (locally advanced cancer – hormone therapy and radiotherapy)

This is the case of Mr G, who was a 64-year-old man who was married and reported low social support. This gentleman has pre-existing health problems of asthma, hypertension and depression. Mr G frequently experienced urinary symptoms over time (see purple, orange and green lines in figure 6.13) and performed four urinary self-management behaviours (see figure 6.14).

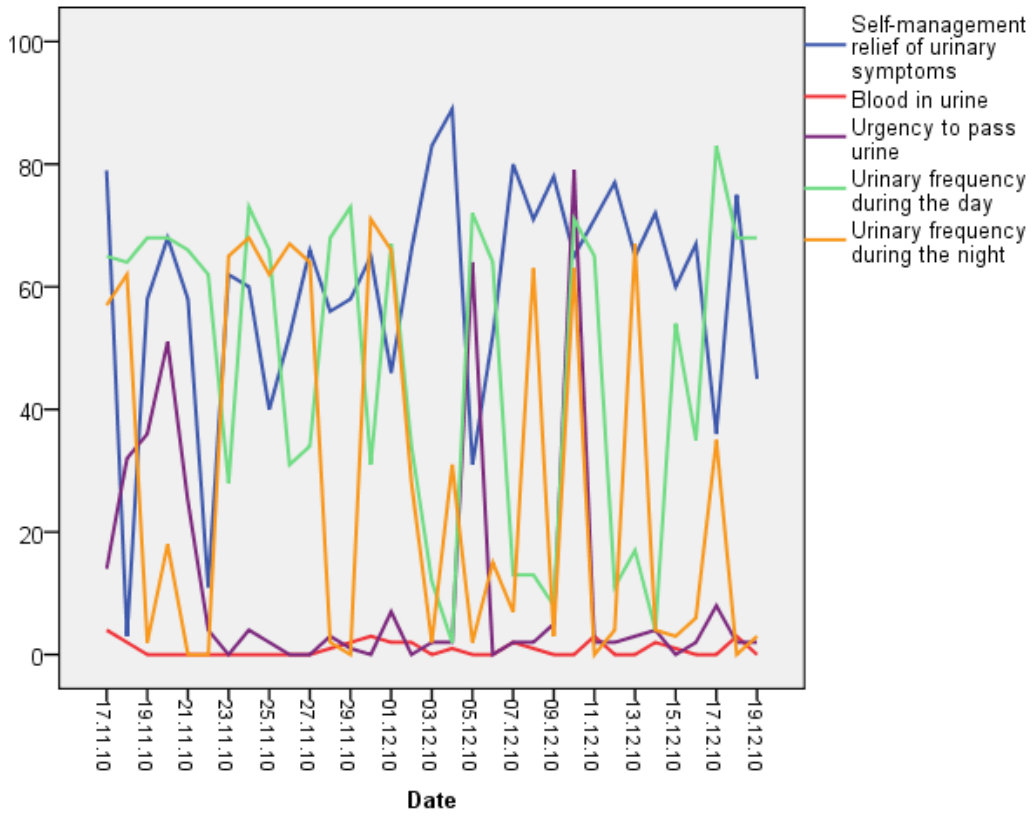


Figure 6.13 Mr G: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

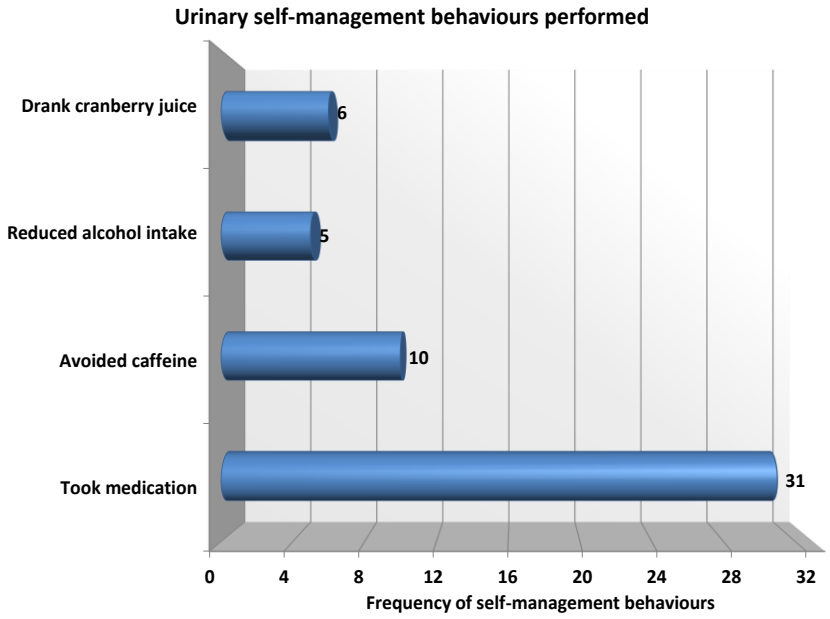


Figure 6.14 Mr G: Distribution of urinary self-management behaviours

No trends of improved urinary symptoms were observed over time. In comparison, Mr F displayed an obvious trend of improved urinary symptoms over time (see figure 6.11), but Mr G did not, and both men had the same stage of cancer and treatment modality. The difference in symptoms could be explained by toxicities following radiotherapy, but could also be associated with social support. Mr F had high social support and mobilised his social support as self-management behaviour to relieve his symptoms, whereas Mr G had low social support and did not use social support in his self-management. It could be that social support improved Mr F's coping efforts when self-managing his symptoms, but this is speculative.

Constipation was frequently experienced by Mr G (see green line in figure 6.15) and three self-management behaviours performed (see figure 6.16). Good self-management of constipation can be seen during 02.12.10 to 06.12.10 (see blue line in figure 6.15) but overall constipation did not improve over time.

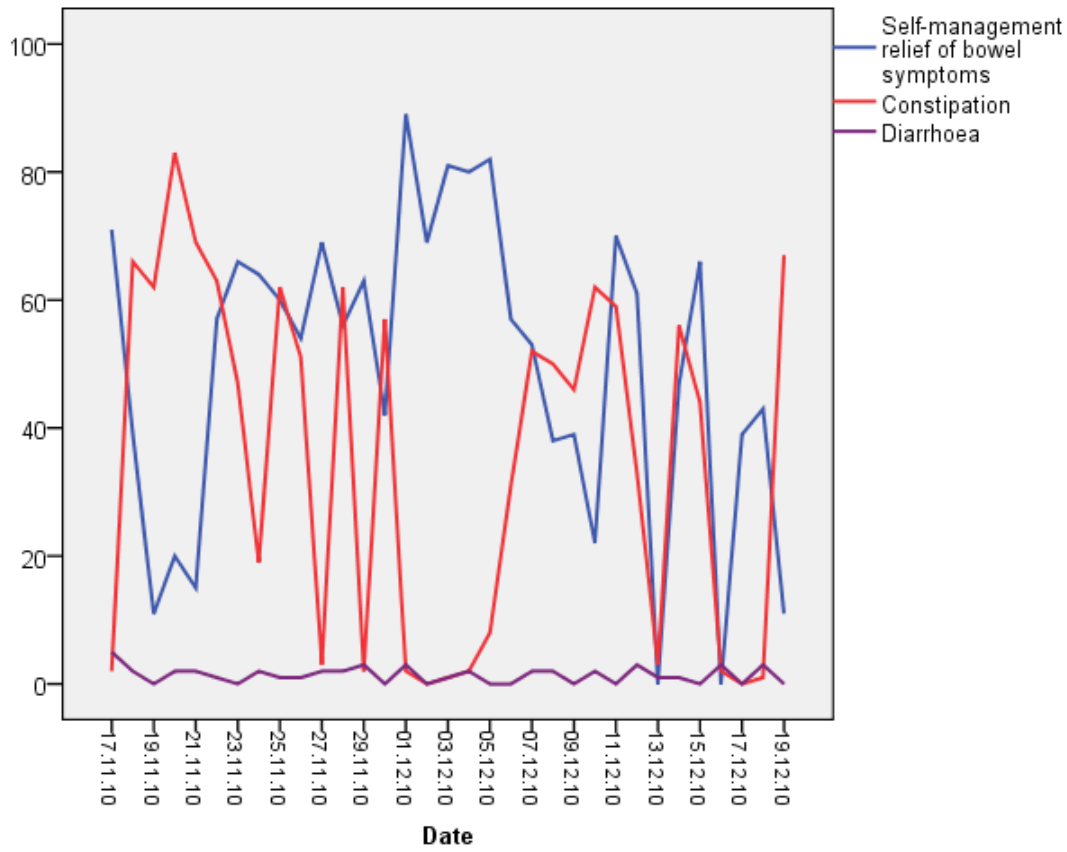


Figure 6.15 Mr G: Frequency of bowel symptoms and self-management relief of bowel symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

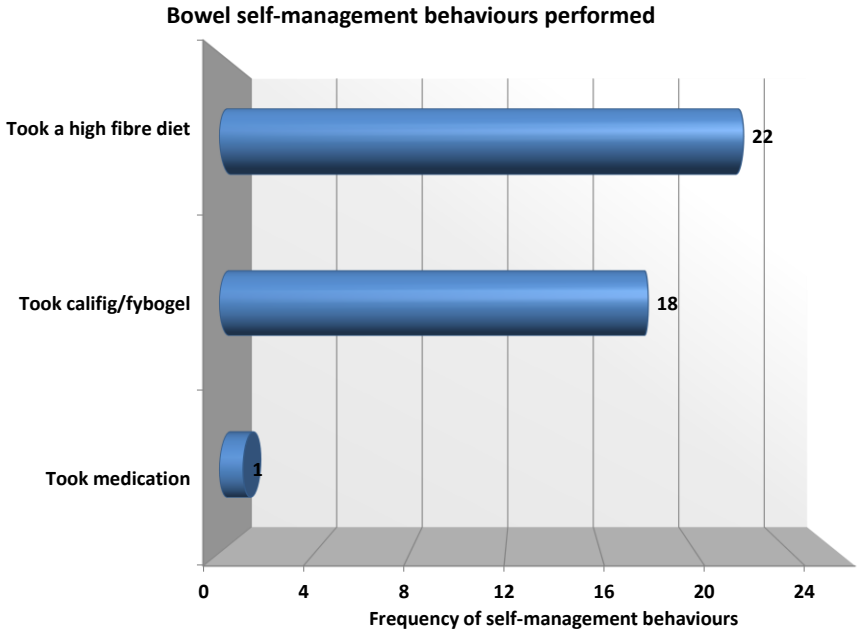


Figure 6.16 Mr G: Distribution of bowel self-care behaviours

Self-management was performed for additional symptoms which included: bowel complaints, sleeping, and stress problems (see table 6.7).

Table 6.7 Mr G: Additional symptoms, self-management behaviours and relief

Date	Symptom	Self-management behaviour	Relief (0-100)
19.11.2010	Poor sleeping pattern	Took more amitriptyline to help sleep through the night	89
25.11.2010	Bleeding from anus	Applied anusol ointment to anus	62
28.11.2010	Poor sleeping pattern	Had a little whisky	60
03.12.2010	Frequent toilet visits	Took larger dose of amitriptyline 100mg	69
14.12.2010	Poor sleeping pattern caused by stress	Took a large whisky before bedtime	66
19.12.2010	Problems with relaxation	Took a large whisky before bedtime	81

A higher score displayed is interpreted as higher relief of self-management

Mr H (locally advanced cancer – hormone therapy and radiotherapy)

Mr H was a 73-year-old man who was single and reported high social support. Mr H frequently experienced urinary symptoms over time (see red, green, orange and purple lines in figure 6.17). From 07/02/20011 to 19/02/2011, five urinary self-management behaviours were performed (see figure 6.18) with good relief (see blue line in figure 6.17), but his self-management did not alleviate his urinary symptoms. Mr H did not report any urinary self-management after 19/02/2011 and therefore,

the interpretation is confined to between 07/02/2011 and 19/02/2011. If the participant did not perform self-management, the diary was programmed not to enquire about relief from self-management behaviours and therefore, the "0 score" (blue line for relief of urinary self-management) in the time series plot is the default. The reasons as to why Mr H discontinued his urinary self-management are unknown, but one explanation could be that he discontinued his self-management strategies because no symptom control was achieved between 07/02/2011 and 19/02/2011 and, consequently, he may have felt that his self-management strategies were inadequate to improve his symptoms and he did not see the benefits in continuing. Alternatively, Mr H may have ignored his symptoms as a form of self-management through avoidance, a form of coping (Ahmad et al., 2005).

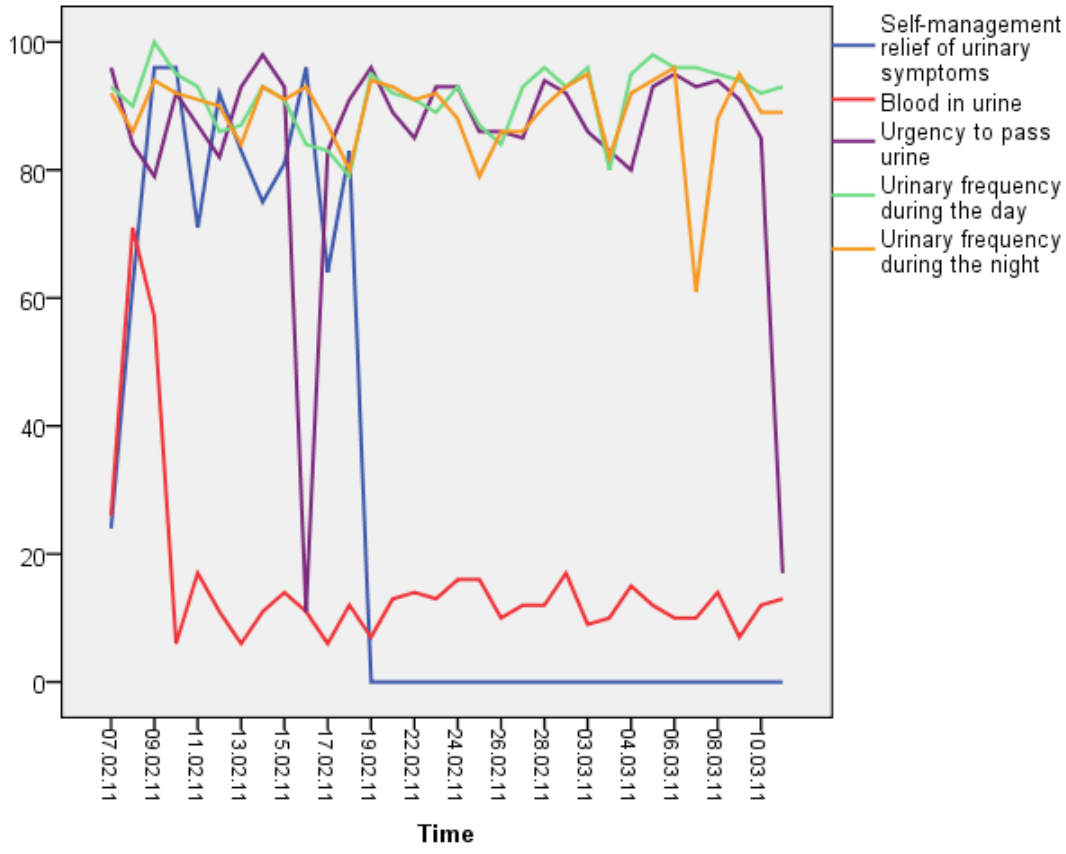


Figure 6.17 Mr H: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

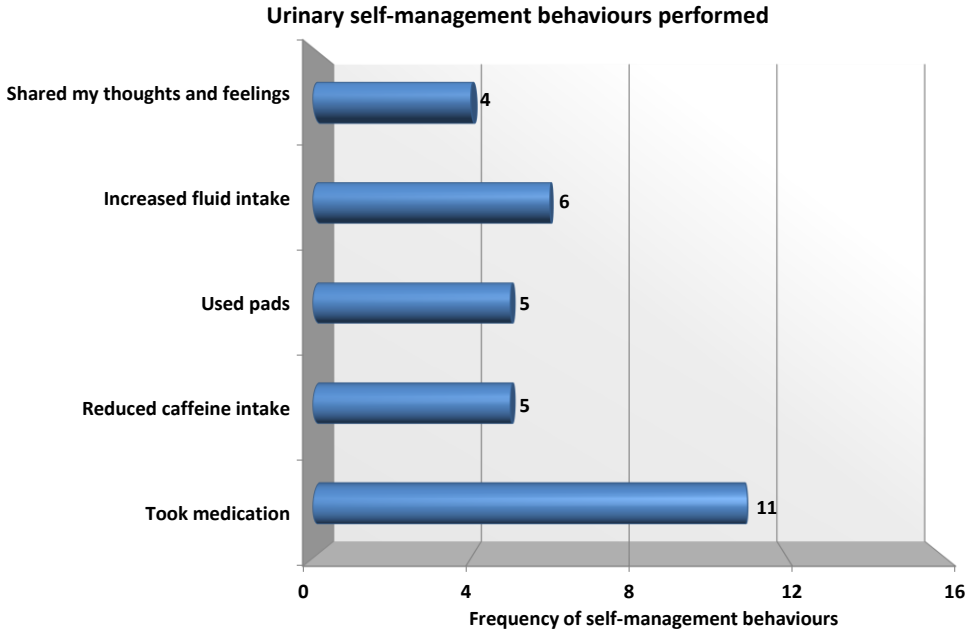


Figure 6.18 Mr H: Distribution of urinary self-management behaviours

Constipation and diarrhoea were frequently experienced symptoms over time (see green and orange lines in figure 6.19). Mr H performed four bowel self-management strategies (see figure 6.20) with good relief, but after 23/02/2011, no bowel self-management was reported. The "0 score" in the time series plot after 23/02/2011 is the default for the electronic diary (same interpretation as Mr H's urinary self-management relief in figure 6.17). The reasons as to why Mr H discontinued his bowel self-management strategies are unclear because he continued to experience bowel symptoms frequently over time.

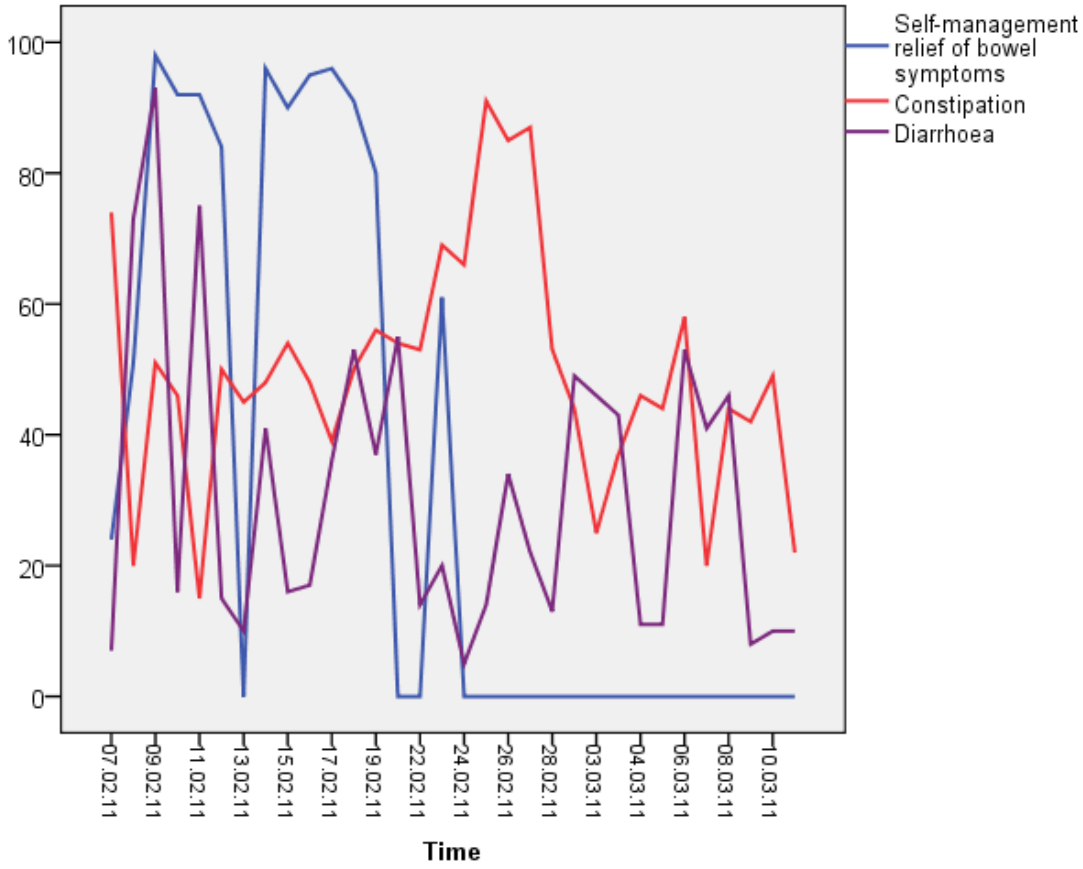


Figure 6.19 Mr H: Frequency of bowel symptoms and self-management relief of bowel symptoms displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

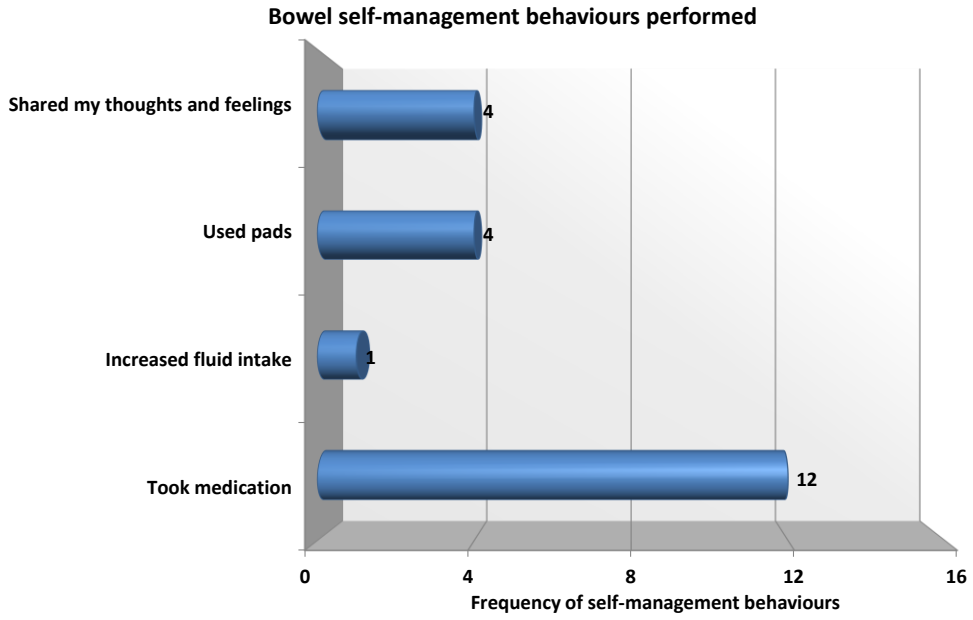


Figure 6.20 Mr H: Distribution of bowel self-management behaviours

Four sexual function self-management behaviours were performed to improve penile rehabilitation, see figure 6.21. Sexual function self-management was performed on eleven days with good relief but his self-management behaviours did not improve his impotence over time, see figure 6.22.

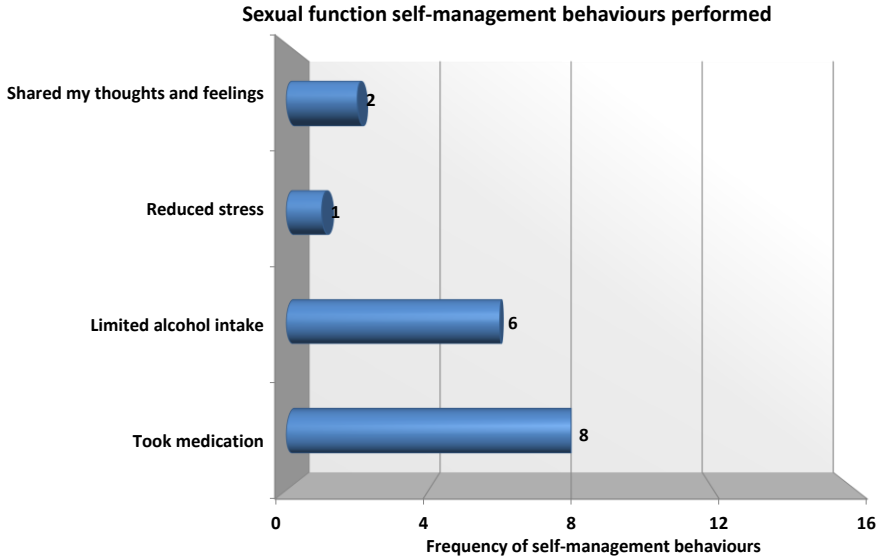


Figure 6.21 Mr H: Distribution of sexual function self-management behaviours

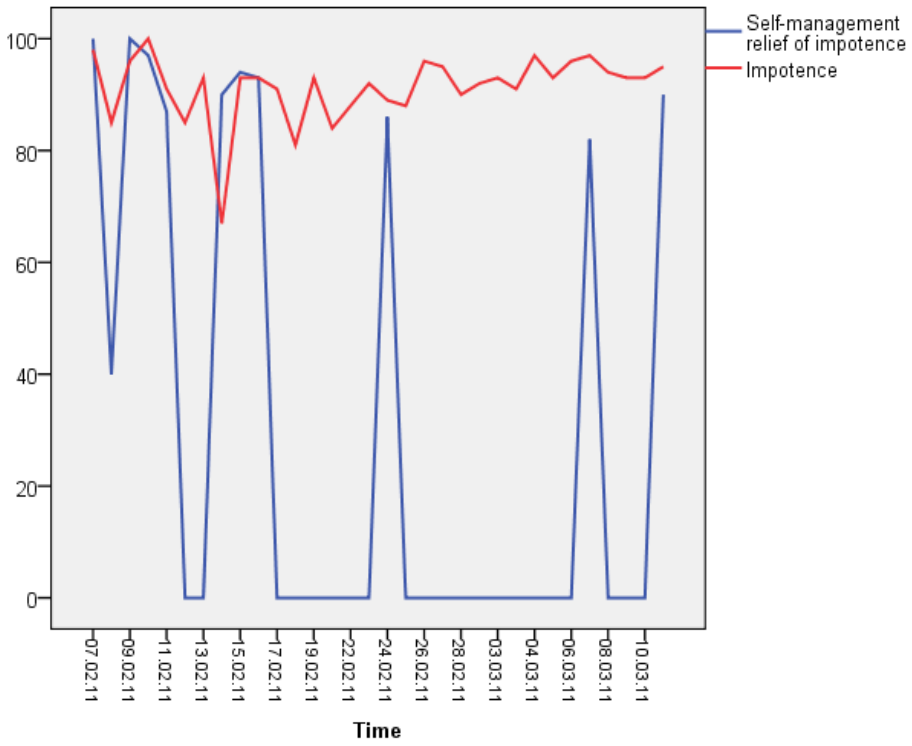


Figure 6.22 Mr H: Frequency of impotence and self-management relief of impotence displaying change over time.
The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr H reported other self-management behaviours for additional problems which are displayed in table 6.8.

Table 6.8 Mr H: Additional symptoms, self-management behaviours and relief.

Date	**Symptom**	**Self-management behaviour**	**Relief (0-100 scale)**
19/02/2011	Radiation burns on my tummy and penis – very painful	Applied Gel from the doctor at Ninewells	20
06/03/2011	Morning sickness	Took anti-sickness tablets	88

A higher score displayed is interpreted as higher relief of self-management

Mr I (locally advanced cancer – hormone therapy and radiotherapy)

Mr I was a 73-year-old man who was single and reported low social support. This man experienced four urinary symptoms over time (displayed in figure 6.23) and performed six urinary self-management behaviours (see figure 6.24). No obvious trend of improved symptom relief was achieved from self-management strategies (see blue line in figure 6.23). Similar to Mr B and Mr G, Mr I also had low social support and all three men identified inadequate symptom relief from their self-management behaviours. This commonality will be further discussed in the general discussion.

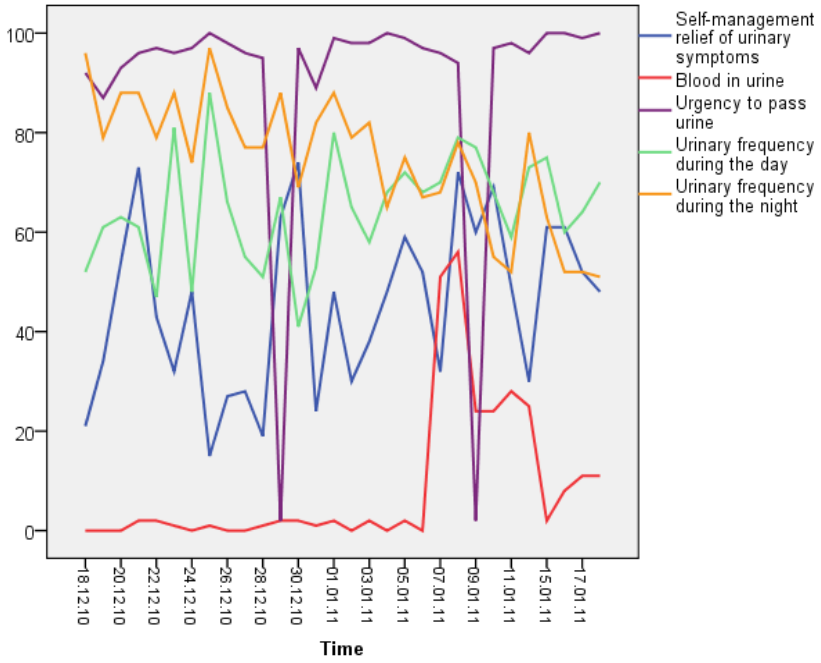


Figure 6.23 Mr I: Frequency of urinary symptoms and self-management relief of urinary symptoms displaying change over time.
The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

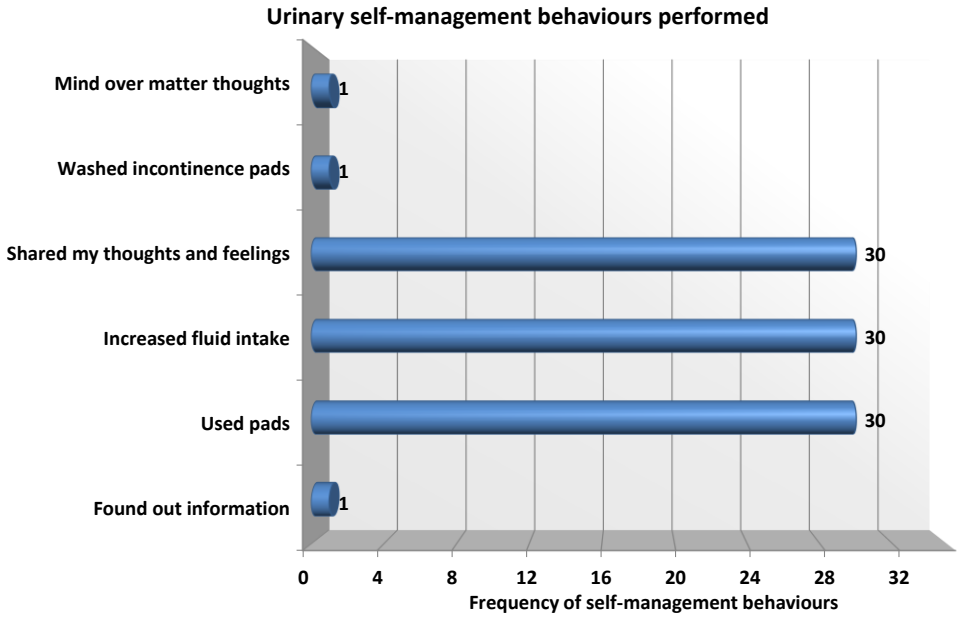


Figure 6.24 Mr I: Distribution of urinary self-management behaviours

Eight bowel self-care actions were performed (see figure 6.25) with good relief from constipation over time (see blue see figure 6.26).

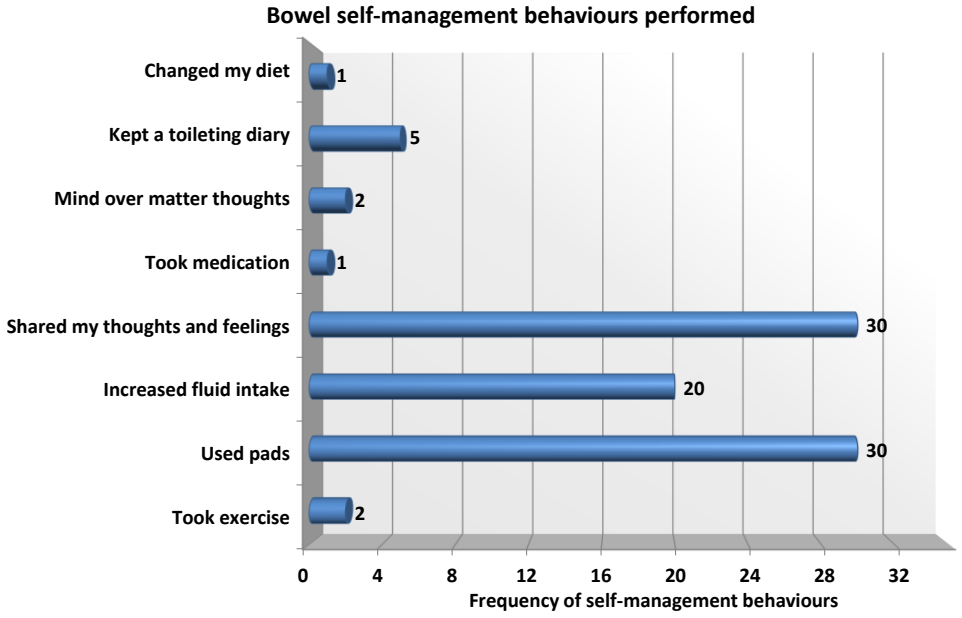


Figure 6.25 Mr I: Distribution of bowel self-management behaviours

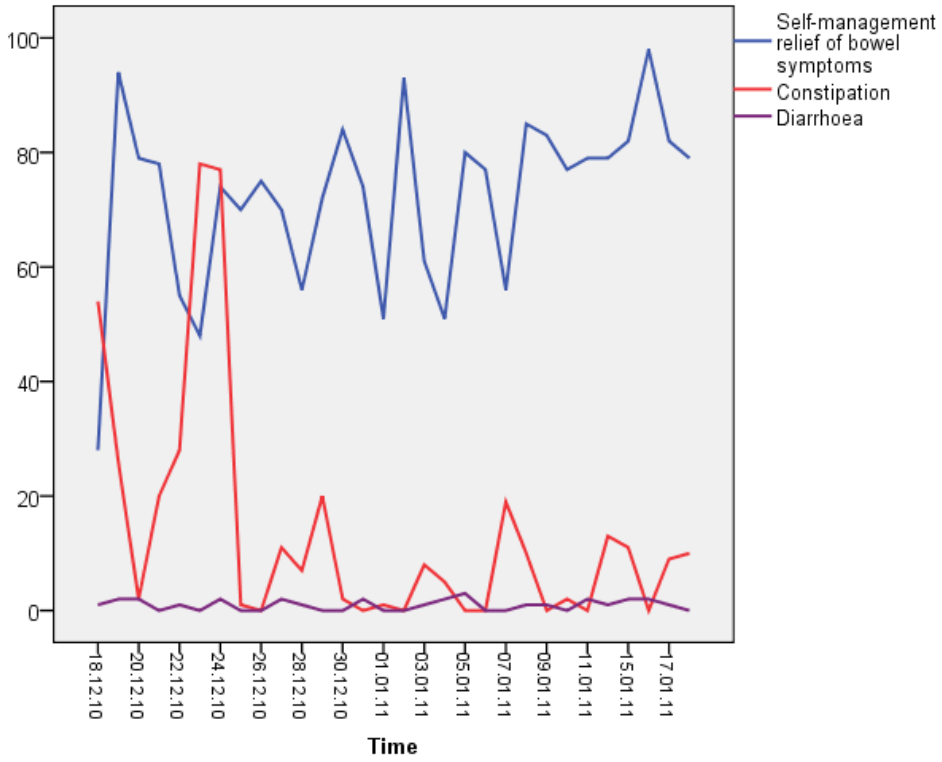


Figure 6.26 Mr I: Frequency of bowel symptoms and self-management relief of bowel symptoms displaying change over time.
The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr I experienced impotence frequently (see red line in figure 6.27) and performed sexual function self-management on one day. Taking medication was the only self-management behaviour reported and he reported little relief from this (see blue line in figure 6.27).

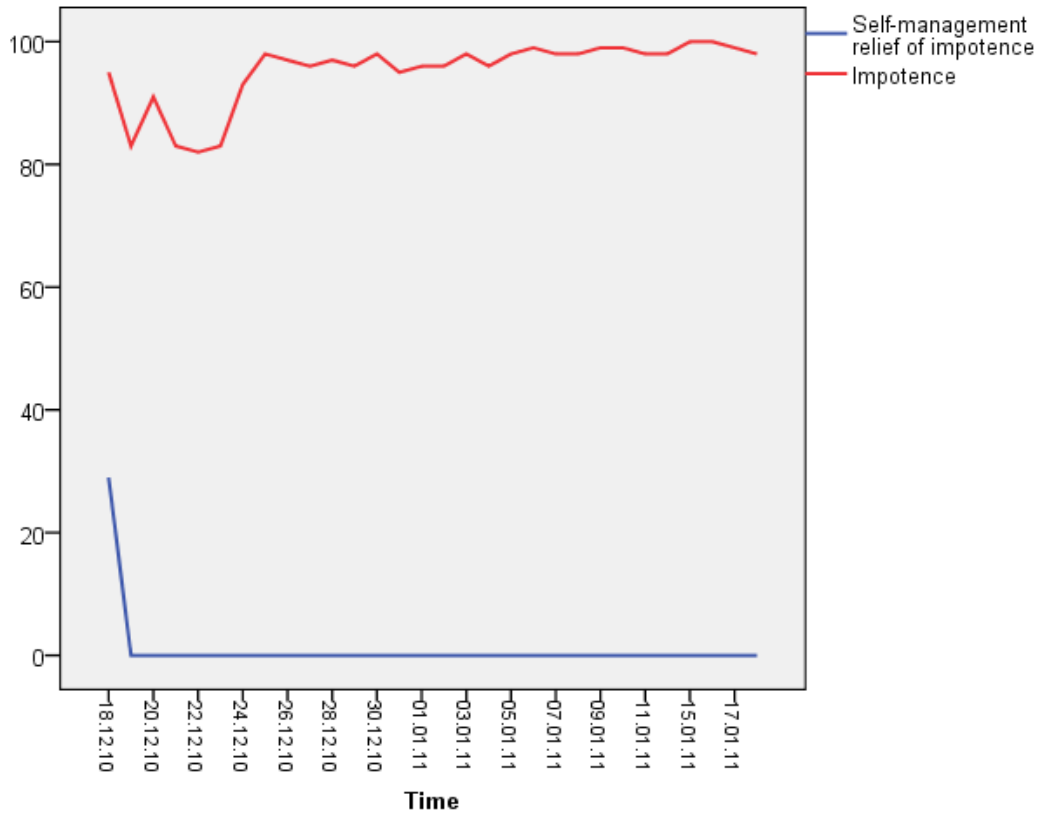


Figure 6.27 Mr I: Frequency of impotence and self-management relief of impotence displaying change over time.
The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom and better relief of self-management actions.

Mr I performed other self-management to relieve symptoms related to the after effects of radiotherapy (see table 6.9). Generally, his self-management behaviours had little relief in alleviating his discomfort.

Table 6.9 Mr I: Additional symptoms, self-management behaviours and relief.

Date	Symptom	Self-management behaviour	Relief (0-100 scale)
18.12.2010	Friction soreness tip of penis – from radiotherapy effects	Applied aqueous cream (am) and wiped the tip with tissue after urinating	29
23.12.2010	Friction discomfort at glands of penis	Application of savlon and I do not know if it is at all effective but the condition worries me	25

A higher score displayed is interpreted as the higher relief of self-management

Mr J (metastatic cancer – hormone therapy)

This is the case of Mr J who was a 73-year-old married man with low social support. This man did not perform any self-management behaviours over the course of his data collection. This man frequently experienced a number of urinary symptoms and impotence over time (see figure 6.28). The reasons as to why Mr J did not perform self-management behaviours to relieve his symptoms are unclear. One possible explanation could be that Mr J experienced inadequate support to help him to self-manage his condition, but alternative explanations will be addressed in the discussion.

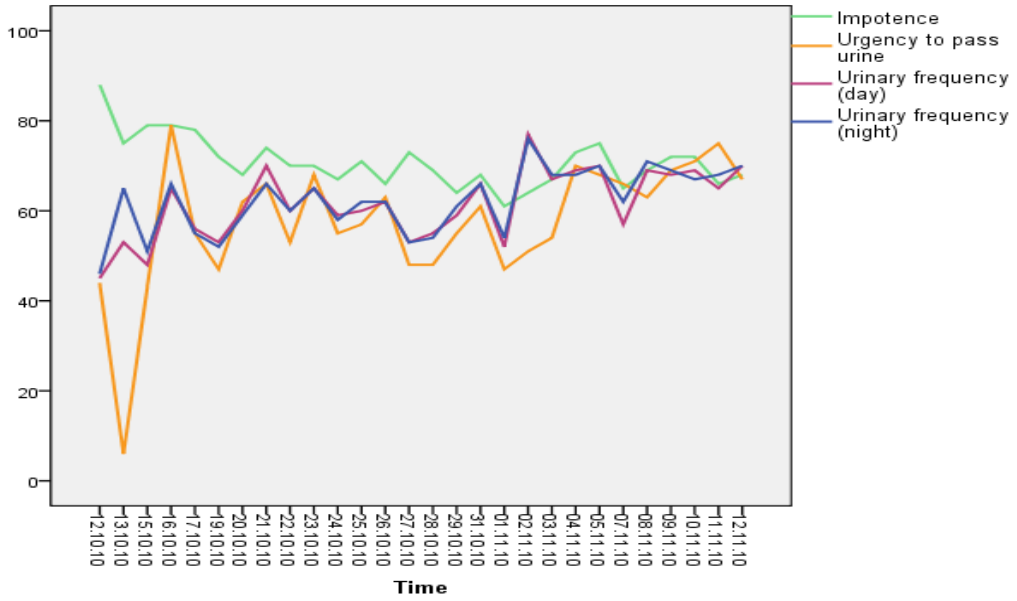


Figure 6.28 Mr J: Most frequent symptoms experienced over time
The ratings (0–100). A higher score displayed is interpreted as a higher frequency of the symptom

Mr K (metastatic cancer – hormone therapy)

Mr K was a 72-year-old married man with high social support. Similar to Mr J, Mr K did not perform any self-management behaviours to relieve symptoms experienced (see figure 6.29 for Mr K's most frequent symptoms). The reasons as to why Mr K did not perform self-management strategies are unclear, but explanations will be addressed in the discussion. An interesting comparison between Mr K and Mr J is that both men experienced symptoms, but Mr J experienced more frequent symptoms compared to Mr K. Both men had similar clinical characteristics but Mr J had low social support while Mr K had high support. The relationship between social support and self-management will be explored in the discussion.

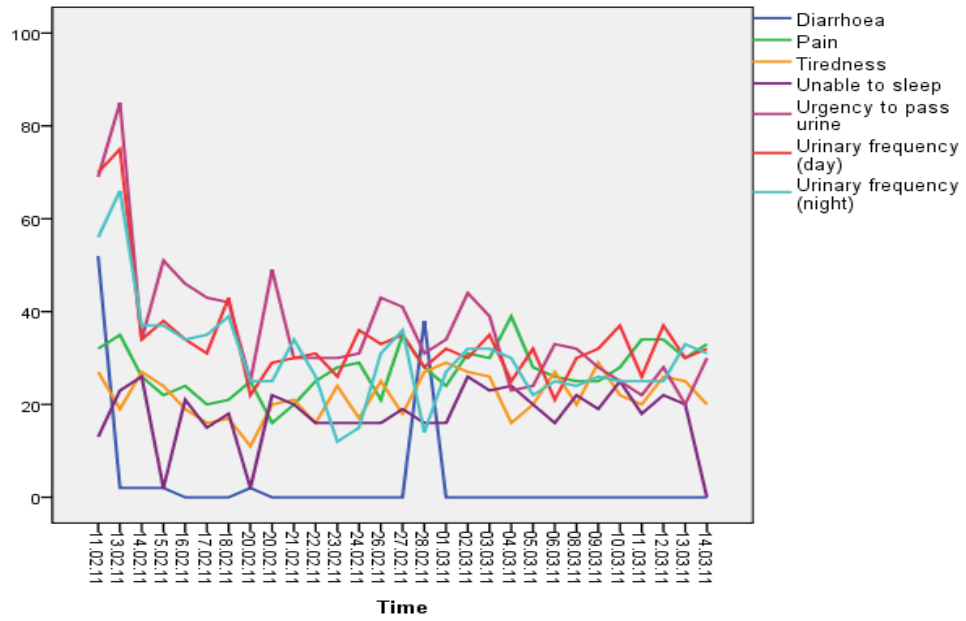


Figure 6.29 Mr K: Most frequent symptoms experienced over time.
The ratings (0 – 100). A higher score displayed is interpreted as a higher frequency of symptom

In summary, men performed a variety of self-management behaviours with the most frequent self-management behaviours being performed by men who had received surgery and radiotherapy (see table 6.4). The number of days that self-management was performed varied between the participants as did the relief of their self-management. Sexual function self-management was infrequently performed across the eleven case studies and the reasons for this are unclear. Alternative explanations will be addressed in the general discussion. A commonality was identified among the men (Mr B, Mr G, Mr I) who had low social support and reported inadequate symptom relief of their self-management behaviours. The relationship between social support and self-management will be explored in discussion. Moreover, differences and similarities between the eleven case studies will be discussed in the general discussion, as will the limitations of the electronic diary approach.

6.5.5 What are the daily social supportive experiences in real time and do they change over time?

Changes in perceived availability of social support, received social support and satisfaction with social support was assessed over time within the context of each case study.

Mr A (localised prostate cancer – active surveillance)

Mr A reported high received and perceived social support over time (see the blue and green lines in figure 6.30). At the start of data collection (see the red line) a reduced score in satisfaction with social support is observed, but overall Mr A was satisfied with his social support over time.

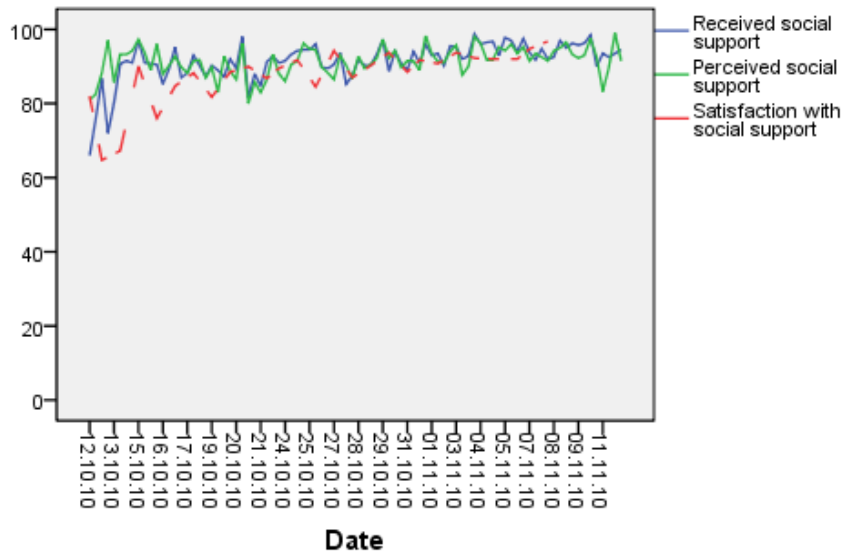


Figure 6.30 Mr A: Perceived, received and satisfaction with social support displaying change over time

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr B (localised prostate cancer – active surveillance)

Mr B received no social support over time (see the blue line in figure 6.31) and had variation in his perceived social support. A trend of reduced satisfaction with social support can be seen (see red line in figure 6.31) over time.

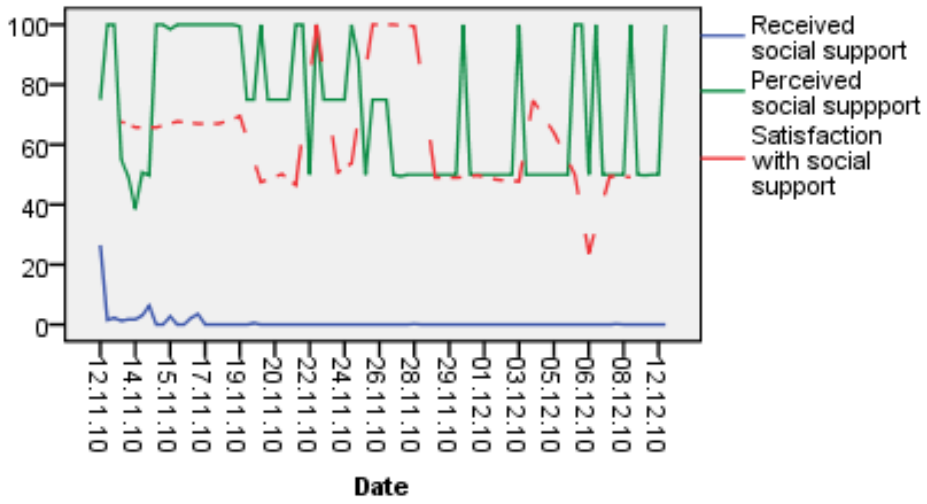


Figure 6.31 Mr B: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr C (localised prostate cancer – laparoscopic radical prostatectomy)

Mr C reported low perceived social support initially, however, following the date 04.02.2011; there is no variation in his perceptions of his social support (see green line in figure 6.32) over time. Mr C received social support at the start of his data collection and after 09.02.2011 he did not receive any social support. Mr C was satisfied with his social support over time.

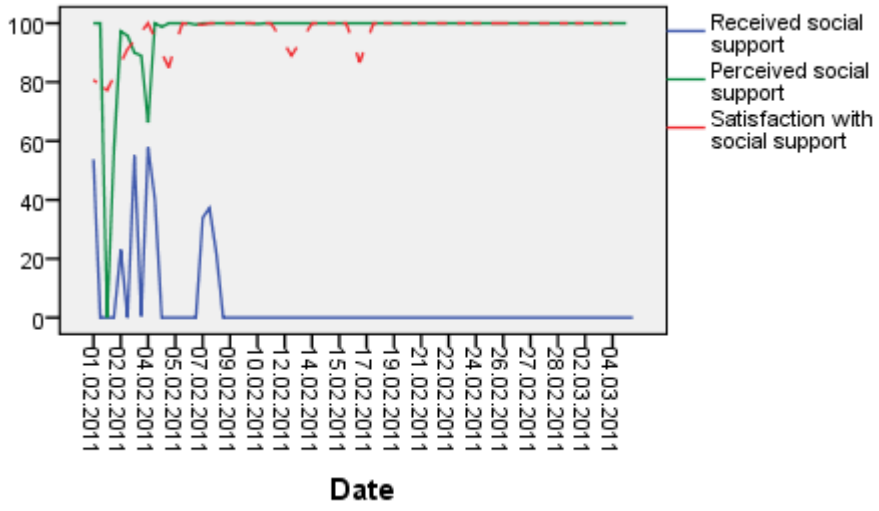


Figure 6.32 Mr C: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr D (localised prostate cancer – laparoscopic radical prostatectomy)

Mr D had variability in the amount of received social support he had at the start of his data collection (see blue line in figure 6.33) but over time he received very little support and had reduced satisfaction levels with social support over time.

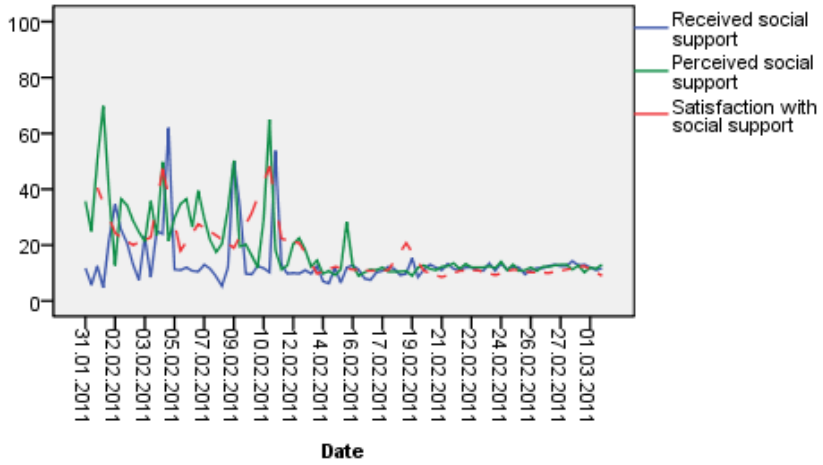


Figure 6.33 Mr D: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr E (locally advanced cancer – hormone therapy and radiotherapy)

Mr E's perceived social support reduced over time (see green line in figure 6.34) and he reported a reduced score for satisfaction with social support over time. Mr E received very little social support throughout the one-month period.

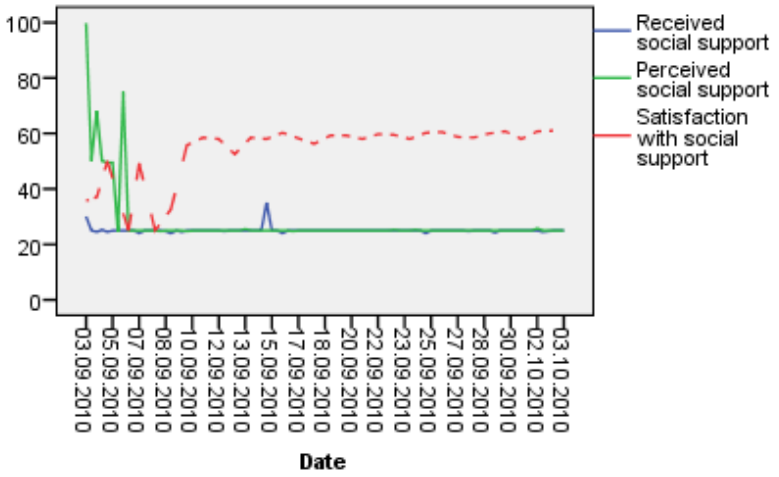


Figure 6.34 Mr E: Perceived, received and satisfaction with social support displaying change over time. The ratings (0–100).

A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr F (locally advanced cancer – hormone therapy and radiotherapy)

Figure 6.35 illustrates very little variance in Mr F's high (>90, 0-100 scale) perceived social support and level of satisfaction over time (see green and red lines). Mr F intermittently received a lot of social support throughout the month (see blue line).

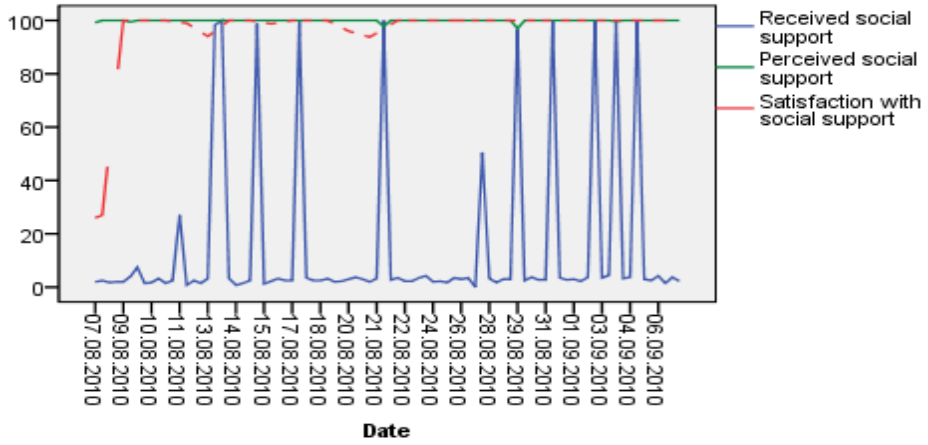


Figure 6.35 Mr F: Perceived, received and satisfaction with social support 1 displaying change over time.

The ratings (0 – 100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr G (locally advanced cancer – hormone therapy and radiotherapy)

Mr G received very little social support and reported a lack of satisfaction with his social support over time (see blue and red lines in figure 6.36). He also had reduced (<50, 0-100 scale) perceived social support with no visual trend over time.

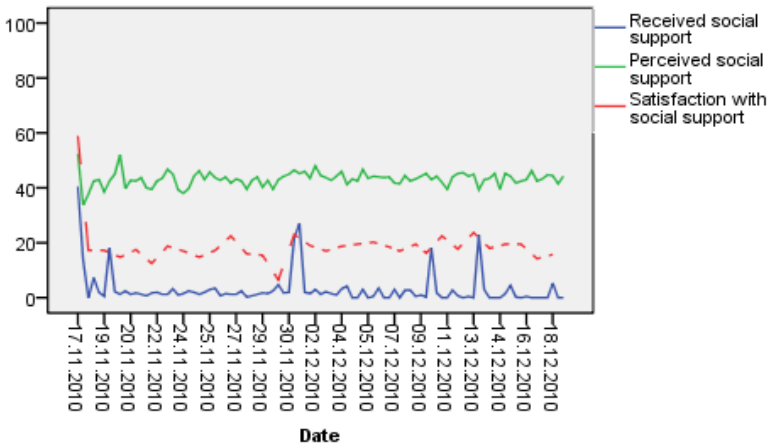


Figure 6.36 Mr G: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr H (locally advanced cancer – hormone therapy and radiotherapy)

Mr H had variation in his perceived social support over time (see green line in figure 6.37). He received little social support over time and reported variability in his level of satisfaction with his social support over time.

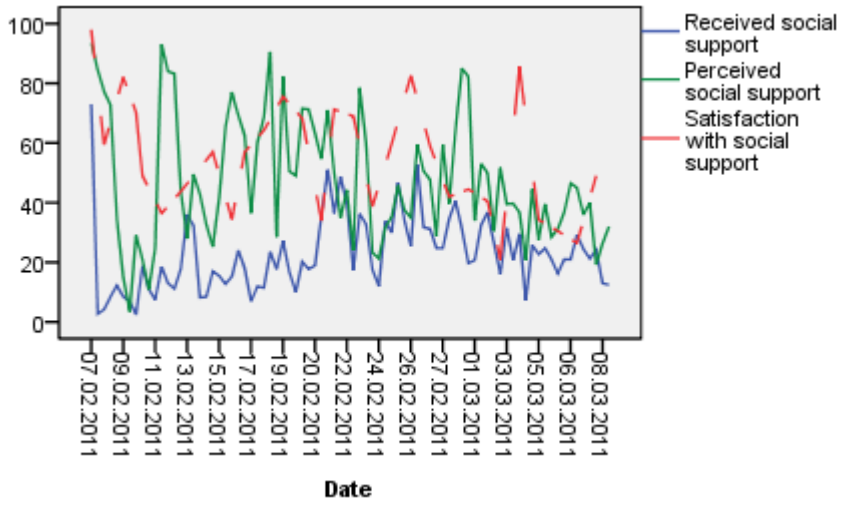


Figure 6.37 Mr H: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr I (locally advanced cancer – hormone therapy and radiotherapy)

Mr I received little social support and had low perceived social support over time (see blue and green lines in figure 6.38). Overall, Mr I reported a lack of satisfaction with his social support (<40, 0-100 scale).

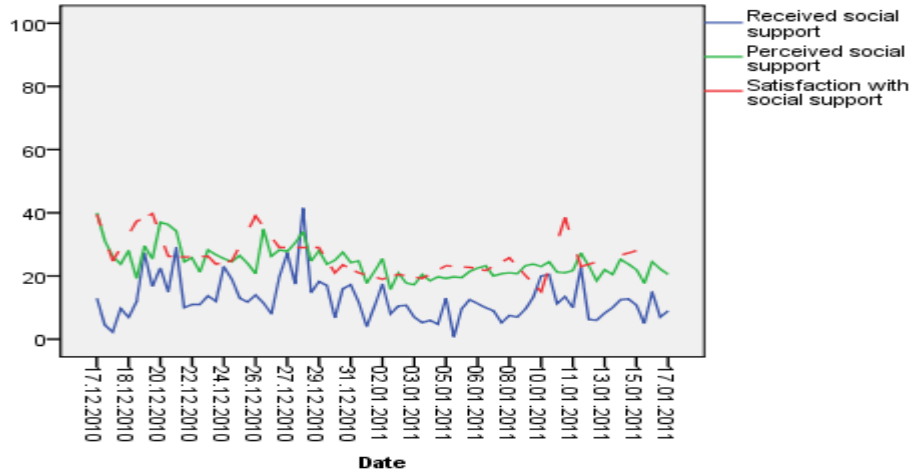


Figure 6.38 Mr I: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr J (metastatic cancer – hormone therapy)

Mr J had little variation between his scores for received, perceived and satisfaction with social support constructs over time (see figure 6.39). Overall, Mr J received social support over.

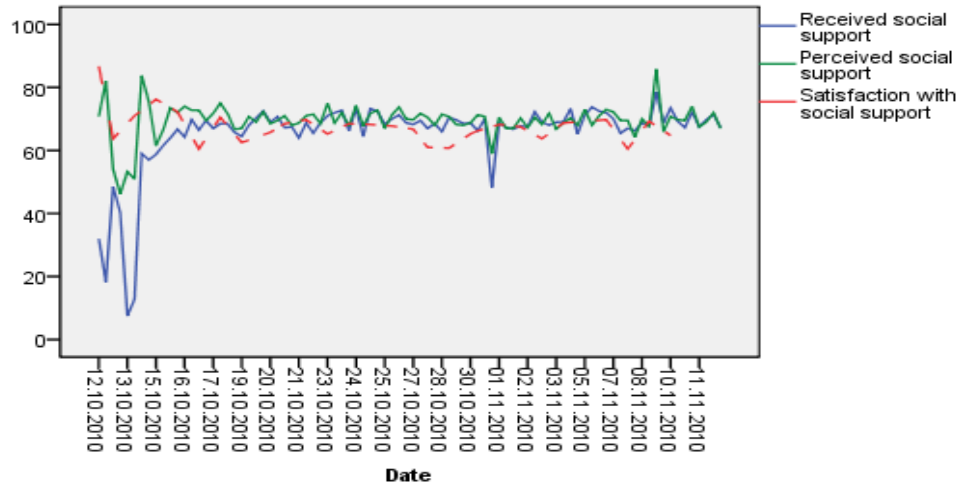


Figure 6.39 Mr J: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

Mr K (metastatic cancer – hormone therapy)

Mr K received little social support and had high perceived social support, with variation in his satisfaction levels with social support over time (see figure 6.40).

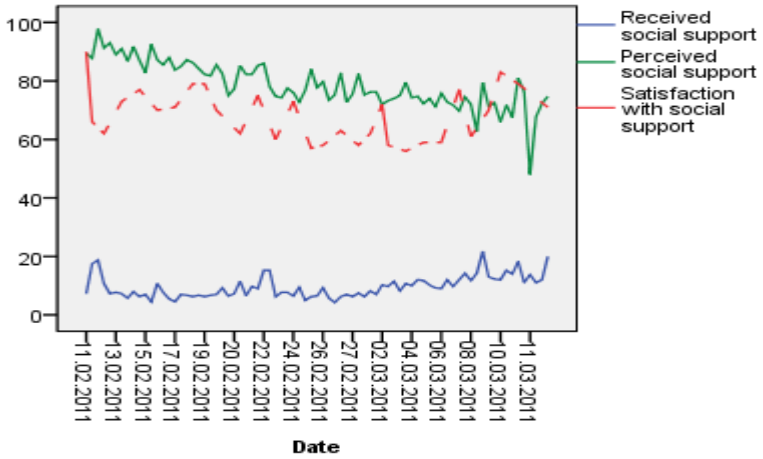


Figure 6.40 Mr K: Perceived, received and satisfaction with social support displaying change over time.

The ratings (0–100). A higher score displayed is interpreted as more social support and a higher level of satisfaction.

This case series of eleven men (Mr A to Mr K) identified that social support constructs displayed a certain degree of variance over time, and demonstrates that traditional instruments cannot accurately detail the intra-individual experience over time and the changes in social support provision. Importantly, all these men (apart from Mr, A, Mr C and Mr F) reported a lack of satisfaction with their support over time and this result would suggest that further research is needed to understand the impact of inadequate support provision on patient reported outcomes, such as negative affect.

6.5.6 Do social supportive experiences moderate/mediate the relationship between coping and mood in real time?

Preliminary Analysis

The standard entry variables were examined for autocorrelation using autocorrelograms (Tabachnick and Fidell, 2007) produced in SPSS. Variables that displayed autocorrelation were pre-whitened based on guidance from (Borckardt et al., 2008, Crane et al., 2003, Cromwell et al., 1994). Pre-whitened variables were examined using autocorrelograms to check that the autocorrelation was successfully removed from the variable. When variables did not meet the assumptions for a particular analysis, transformations were performed (Tabachnick and Fidell, 2007). Descriptive statistics were performed for standard, end-of-day and incident entries for each individual case study. A Pearson product-moment correlation analysis was performed for all of the continuous variables (received social support, perceived social support, positive coping, negative coping, negative affect, positive affect, self-management demand, self-management control, self-management self-efficacy) at the standard data entry enquiry. Prior to each regression analysis the evaluation of the assumptions of a particular analysis were checked (see appendix 6.1 for heuristics used). Mr A's preliminary analyses are detailed in the following section and the remaining preliminary analyses for the ten remaining case studies are detailed in appendix 6.3.

Exemplar of preliminary analysis: Case study Mr A

Mr A is a married 73-year-old gentleman who was diagnosed with localised prostate cancer and on the active surveillance programme.

Preliminary analysis– Mr A

Significant autocorrelations were found for positive affect (at a lag of 3), received social support and self-management control (both at a lag of 1). No other variables in the data series displayed autocorrelation. The pre-whitening procedure was successfully applied to these variables and removed the presence of autocorrelation.

Negative coping displayed positive skewness and kurtosis and the Kolmogorov-Smirnov (K-S) test was significant, $D(88) = 0.169$, $p<0.001$. A square root transformation was applied to negative coping and this reduced the impact of outliers and improved normality of distribution. Self-efficacy was positively skewed due to the presence of one univariate outlier and the transformations were unsuccessful. The outlier value was replaced with the next highest extreme value plus 1 unit (80+1=81), thus the value of 81 was imputed (Tabachnick and Fidell, 2007) and achieved normality, K-M (88) =0.084, P=0.173.

Descriptive statistics – Mr A

Descriptive statistics for the continuous variables are displayed in table 6.10 and 6.11. Mr A reported a high quality of life scores, high received and perceived social support, with overall satisfaction with support. This gentleman had a high level of self-care self-efficacy. No incident entries were completed over the one-month data collection period.

Table 6.10 Mr A: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-management demand	88	1	32	9.44	4.7
Self-management control	88	77	100	90.3	4.6
Positive coping	88	81	100	90.9	4.4
Negative coping	88	0	34.7	12.4	5.5
Negative affect	88	1.6	30.6	9.4	5.7
Positive affect	88	41.6	97.7	78.9	11.2
Self-care self-efficacy	88	79	98.5	90.8	3.8
Received social support	88	66	98.7	91.4	5.3
Perceived social support	88	80	99	91.4	4

All scales are from 0-100. A higher number is interpreted as a higher score of that variable.

Table 6.11 Mr A: End-of-day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

End-of-day entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	27	64.7	96.7	87.5	7.7
Were you able to discuss your thoughts and feelings today?	27	11.0	90.0	64.7	24.1
Did you want to discuss your feelings today?	27	2.0	51.0	15.3	9.9
Overall, self-care self-efficacy	27	86.5	98.0	92.7	3.2
Quality of life	27	70.0	100.0	89.8	5.8

All scales are from 0-100. A higher number is interpreted as a higher score of that variable.

Symptoms were assessed at the end-of-day entry (see table 6.12). A range of symptoms were experienced by Mr A.

Table 6.12 Mr A: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	27	0	47	7.6	8.9
Blood in the urine	27	0	17	5.6	3.9
Diarrhoea	27	0	15	6.1	3.7
Impotence	27	2	45	16.7	10.4
Nausea	27	0	14	6.3	3.9
Pain	27	0	32	6.6	6.1
Tiredness	27	2	47	11.7	9.2
Unable to sleep	27	0	13	7.1	3.6
Urgency to pass urine	27	0	17	7.1	4.3
Urinate frequently during the day	27	0	52	10.8	10.3
Urinate frequently at night	27	0	16	7.4	3.5
Vomiting	27	2	11	5.7	2.8

The ratings are: (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom.

The results of the Pearson product-moment correlation for all the variables at the standard entry are presented in table 6.13 for Mr A.

Table 6.13 Pearson's product moment correlation coefficients between all variables (unaltered and altered variables) for Mr A

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1) Positive coping	1														
2) Negative coping	0.346**	1													
3) SQRT negative coping	0.382**	0.956**	1												
4) Positive affect	0.202	-0.099	-0.142	1											
5) Positive affect $_{(PreW\ lag\ 3)}$	0.192	-0.075	-0.116	0.952**	1										
6) SQRT positive affect $_{(PreW\ lag\ 3)}$	0.156	-0.050	-0.092	0.896**	0.923**	1									
7) Negative affect	-0.430**	0.254*	0.283**	-0.186	-0.168	-0.084	1								
8) SQRT negative affect	0.419**	0.268*	0.299**	-0.183	-0.15	-0.069	0.982**	1							
9) Self-efficacy	0.440**	-0.349**	-0.340**	0.279**	0.253*	0.277**	-0.338**	-0.353**	1						
10) Received social support	0.361**	-0.257*	-0.211*	0.193	0.150	0.187	-0.319**	0.347*	0.385**	1					
11) Received social support $_{(PreW\ lag\ 1)}$	0.165	-0.044	-0.021	0.167	0.154	0.212	-0.116	-0.150	0.093	0.844**	1				
12) Perceived social support	0.447**	-0.282**	-0.276**	0.216*	0.191	0.116	-0.405**	-0.425**	0.417**	0.614**	0.426**	1			
13) Demand	0.363**	0.433**	0.445	-0.025	-0.003	0.063	0.391**	0.417**	0.317**	-0.281**	-0.148	-0.417**	1		
14) Control	0.483**	-0.264*	-0.287**	0.144	0.109	0.064	-0.445**	0-.462**	0.493**	0 .581**	0.333**	0.584**	-0.422**	1	
15) Control $_{(PreW\ lag\ 1)}$	0.350**	-0.080	-0.124	0 .092	0.064	0.009	-0.330**	-0.349**	0.241*	0.333**	0.273*	0.379**	-0.350**	0.880*	1

*p<0.05, **p<0.01 (2-tailed)

MODERATIONS

Moderation analyses were performed to test the theoretical model (see figure 6.41) with variables in the standard diary entry (assessed 3 times per day). The assumptions were checked and analyses were only performed with variables correlated with the dependent variable (negative affect) at P values <0.15 (Tabachnick and Fidell, 2007) for each case study.

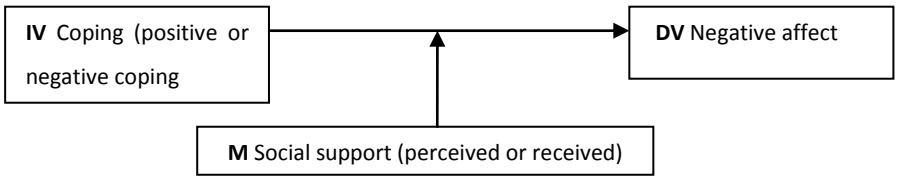


Figure 6.41 Moderation analysis

Mr A (localised prostate cancer – active surveillance)

Positive coping (r= -0.419, P<0.01), negative coping $_{\text{square root}}$ (r= 0.299, P<0.01) and perceived social support (r= -0.425, P<0.01) had a significant correlation with negative affect $_{\text{square root}}$. Received social support $_{\text{(PreW lag 1)}}$ did not have an association with negative affect $_{\text{square root}}$ (P>0.15) and therefore, the moderation analyses were only performed with perceived social support (see table 6.13).

A significant main effect was found for positive coping and perceived social support (unstandardized regression co-efficient -0.257 and -0.227, respectively) on negative affect $_{\text{square root}}$, explaining 23.4% of variance of negative affect $_{\text{square root}}$, (F-ratio 13.864, P<0.001). Perceived social support did not moderate the relationship between positive coping and negative affect (see table 6.14).

Table 6.14 Mr A Moderation: Positive coping and negative affect $_{\text{square root}}$ moderated by perceived social support

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	2.954	0.080			
Z score positive coping	0.246**	0.090**	-0.286**		
Z score perceived social support	-0.255**	0.090**	-0.297**	0.246**	0.228**
Step 2					
Constant	2.909	0.087			
Z score positive coping	-0.257**	0.090**	-0.299**		
Z score perceived social support	-0.227*	0.093*	-0.264*		
Z score positive coping X Z score perceived social support	0.101	0.078	0.125	0.261**	0.234**

Dependant variable negative affect $_{\text{square root}}$ *p<0.05, **P<0.01 n=88

Perceived social support had a significant relationship with negative affect $_{\text{square root}}$, explaining 19.8% of the variance of negative affect $_{\text{square root}}$ (F-ratio 11.722, P<0.001). Perceived social support did not moderate the relationship between negative coping and negative affect (see table 6.15).

Table 6.15 Mr A Moderation: Negative coping $_{\text{square root}}$ and negative affect $_{\text{square root}}$ moderated by perceived social support

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	2.931	0.085			
Z score negative coping $_{\text{square root}}$	0.169	0.086	0.197		
Z score perceived support	-0.318**	0.086**	-0.371**	0.216**	0.198**
Step 2					
Constant	2.931	0.085			
Z score negative coping $_{\text{square root}}$	0.164	0.086	0.191		
Z score perceived support	-0.304**	0.087**	-0.354**		
Z score negative coping $_{\text{square root}}$ X Z score perceived support	-0.084	0.082	-0.100	0.226**	0.198**

Dependant variable negative affect $_{\text{square root}}$ *p<0.05, **P<0.01 n=88

Mr B (localised prostate cancer – active surveillance)

Positive coping $_{(\text{preW lag 1})}$ (r= -0.360, P<0.01) and received social support (r=0.199, P=0.073, p=<0.15) was associated with negative affect $_{(\text{preW lag 2})}$. Negative coping $_{(\text{preW lag 3})}$ and perceived social support $_{(\text{preW lag 1})}$ did not have any associations with negative affect $_{(\text{preW lag 2})}$. The analyses were conducted with positive coping and received social support only.

Received social support moderated the relationship between positive coping $_{(\text{preW lag 1})}$ and negative affect $_{(\text{preW lag 2})}$ (see table 6.16) which explained 25.8% of the variance of negative affect $_{(\text{preW lag 2})}$, F-ratio=10.379, P<0.001 (see figure 6.42 for the interaction effect). Low positive coping is associated with high negative affect (mood) under conditions of low received social support, but high positive coping is associated with high negative affect when received social support is high.

Table 6.16 Mr B Moderation: Positive coping $_{PreW\ 1}$ and negative affect $_{PreW\ 2}$ moderated by received social support

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	0.159	0.194			
Z score positive coping $_{PreW\ 1}$	-0.732**	0.186**	-0.402**		
Z score received support	1.486*	0.576*	0.264*	0.197**	0.177**
Step 2					
Constant	-0.072	0.199			
Z score positive coping $_{PreW\ 1}$	-0.354	0.215	-0.194		
Z score received support	0.553	0.624	0.098		
Z score positive coping $_{PreW\ 1}$ X Z score received support	2.525**	0.814**	0.384**	0.285**	0.258**

Dependant variable negative affect $_{preW\ 2}$ *p<0.05, **P<0.01 n=83

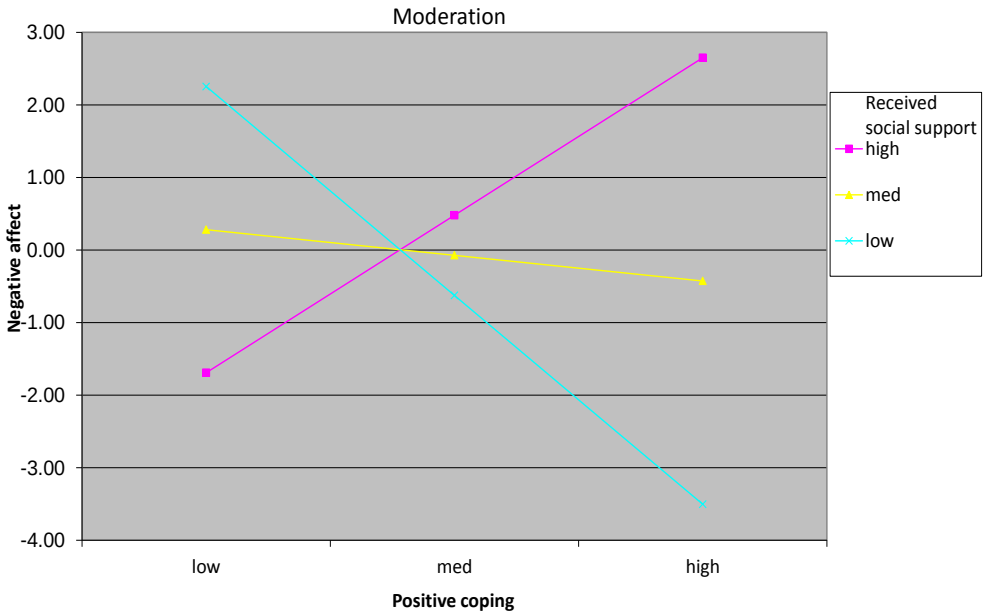


Figure 6.42 Mr B: Positive coping $_{(preW\ lag\ 1)}$ and negative affect $_{(preW\ lag\ 2).}$ moderated by received social support

Mr C (localised prostate cancer – laparoscopic radical prostatectomy)

Negative coping (r=0.440, P<0.001), positive coping (r= -0.525, P<0.001) and received social support $_{(preW\ lag\ 1)}$ (r= 0.192, P=0.090, at P<.15) were correlated with square root negative affect $_{(PreW\ lag\ 1)}$. No associations were found with perceived social support, and therefore, the analyses were performed with received social support only.

Only positive coping was found to have a significant relationship with negative affect (see table 6.16). No moderation effects were found for positive coping and received social support $_{(preW\ lag\ 1)}$ on negative affect $_{(preW\ lag\ 1)}$ (see table 6.17).

Table 6.17 Mr C Positive coping and negative affect $_{(preW\ lag\ 1)}$. moderated by received social support $_{(preW\ lag\ 1)}$.

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	3.358	0.072			
Z score positive coping	-0.376**	0.074**	-0.507**		
Z score received support $_{PreW\ 1}$	0.064	0.074	0.085	0.282**	0.263**
Step 2					
Constant	3.348	0.073			
Z score positive coping	-0.348**	0.081**	-0.469**		
Z score received support $_{PreW\ 1}$	0.034	0.083	0.045		
Z score positive coping X Z score received support $_{PreW\ 1}$	-0.047	0.056	-0.101	0.289**	0.260**

Dependant variable square root negative affect $_{(preW\ lag\ 1)}$*p<0.05, **P<0.01, n=79

Received social support $_{(preW\ lag\ 1)}$ moderated the relationship between negative coping and square root negative affect $_{(preW\ lag\ 1)}$, see table 6.18. The moderation interaction explained 22.3% of the variance of square root negative affect $_{(preW\ lag\ 1),}$ F-ratio 8.468, P<0.001 (see figure 6.43 for interaction effect). Low negative coping is associated with high negative affect under conditions of low received social support.

Table 6.18 Mr C: Results moderation of negative coping and received social support $_{(preW\ lag\ 1)}$ on square root negative affect $_{(preW\ lag\ 1)}$.

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	3.347	0.076			
Z score negative coping	0.332**	0.085**	0.422**		
Z score received support $_{PreW\ 1}$	0.044	0.081	0.059	0.197**	0.176**
Step 2					
Constant	3.309	0.076			
Z score negative coping	0.278**	0.086**	0.354**		
Z score received support $_{PreW\ 1}$	-0.122	0.105	-0.163		
Z score negative coping X Z score received support $_{PreW\ 1}$	0.133*	0.056*	0.346*	0.253**	0.223**

Dependent variable square root negative affect $_{(preW\ lag\ 1)}$*p<0.05, **P<0.01, n=79

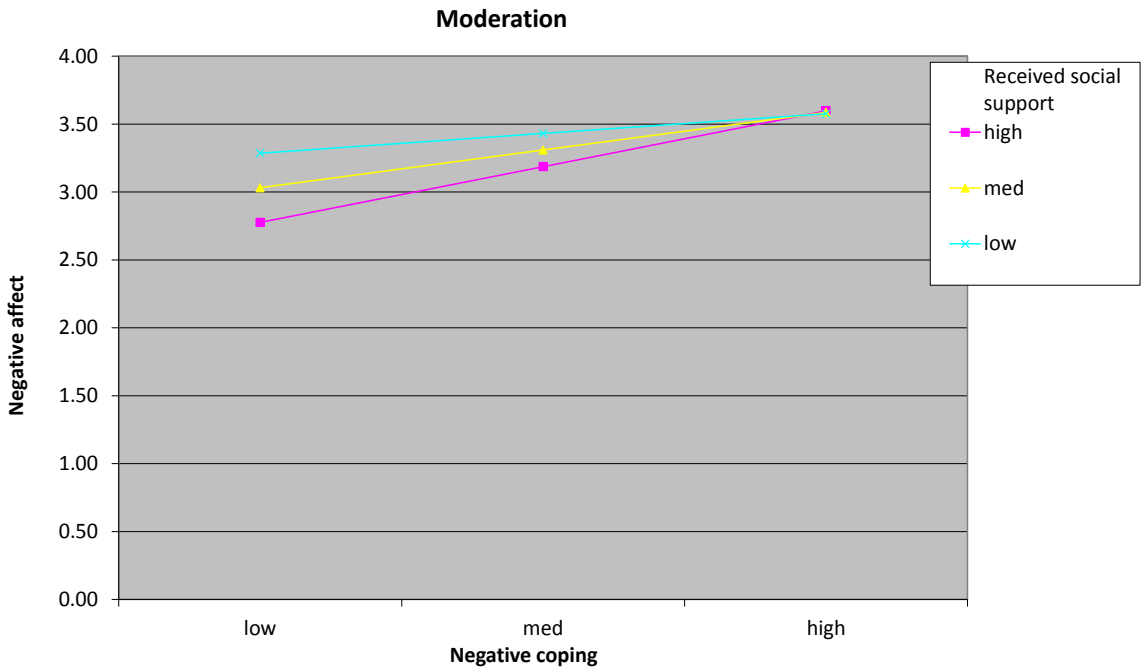


Figure 6.43 Mr C: Negative coping and negative affect $_{(preW\ lag\ 2)}$. moderated by received social support

Mr D (localised prostate cancer – laparoscopic radical prostatectomy)

Positive coping (r=0.020, P=0.845), square root negative coping $_{(preW\ lag\ 2)}$ (r=0.124, P=0.234) and perceived social support $_{(preW\ lag\ 1)}$ (r=0.073, P=0.481) was not significantly correlated with negative affect $_{(preW\ lag\ 1)}$. The analyses were not performed because of the non-association between the predictor variables (positive coping and negative coping) and the dependent variable (negative affect).

Mr E (locally advanced prostate cancer – hormone therapy and radiotherapy)

For Mr E, negative affect did not have any associations with positive coping, negative coping and perceived social support variables, but a significant relationship was found with negative affect and received social support (r=0.440, p<0.05). The analyses were not performed because of the non-association between the predictors and the dependent variable.

Mr F (locally advanced prostate cancer – hormone therapy and radiotherapy)

Negative coping $_{(log)}$ (r=0.266, P<0.05) had a significant association with negative affect $_{(log),}$ but positive coping (r=-0.048, P=.663) was unrelated to negative affect $_{(log)}$. Received and perceived social support was associated with negative affect $_{(log)}$ at P<0.15 level.

A significant moderation effect was found between negative coping $_{(log)}$ and received social support and explained 11.9% of the variance of negative affect $_{(log)}$, F-ratio 4.456, p=0.006 (see table 6.19). High negative coping is associated with negative affect (mood) under conditions of low received social support (see figure 6.44 for the interaction effect).

Table 6.19 Mr F: Negative coping $_{(log)}$ and negative affect $_{(log)}$ moderated by received social support

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	2.109	0.084			
Z score negative coping $_{(log)}$	0.193*	0.085*	0.254*		
Z score received support	-0.091	0.086	-0.188	0.087*	0.061*
Step 2					
Constant	2.085	0.082			
Z score negative coping $_{(log)}$	0.412**	0.123**	0.542**		
Z score received support	-0.101	0.083	-0.132		
Z score negative coping $_{(log)}$ X Z score received support	-0.136*	0.057*	-0.388**	0.153*	0.119*

Dependant variable negative affect $_{(log)}$ *p<0.05, **p<0.01 n=78

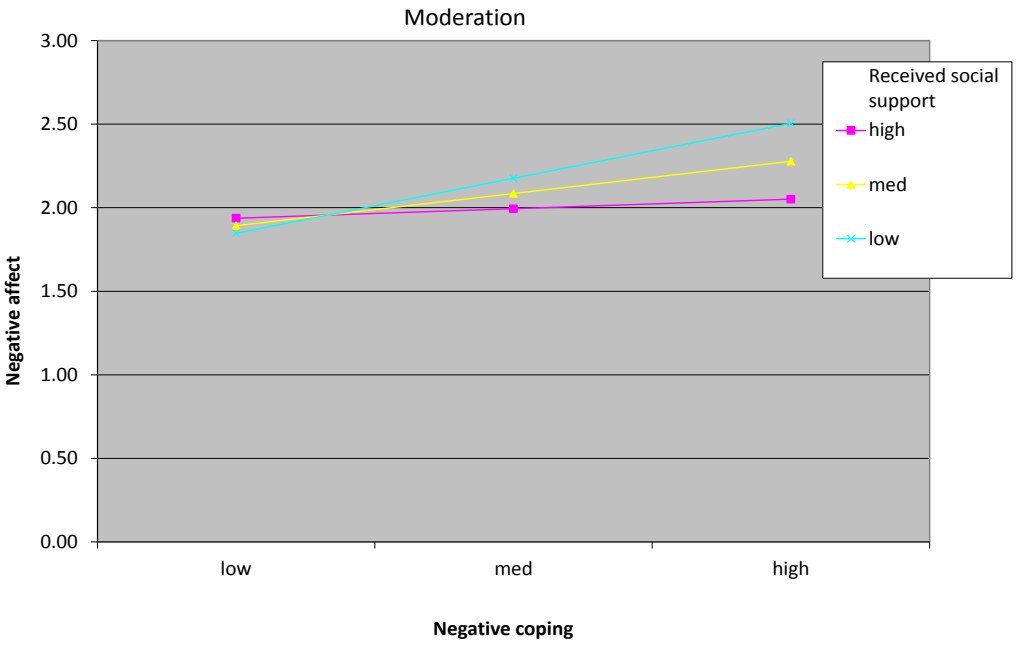


Figure 6.44 Mr F: Negative coping $_{(log)}$ and negative affect $_{(log)}$ moderated by received social support

The moderation was repeated with perceived social support and a significant moderation interaction effect was found (see table 6.20). The relationship between negative coping and negative affect was moderated by perceived social support which explained 11.9% of the variance of negative affect $_{(log)}$, (F-ration 4.674, p=0.005). The interaction effects are displayed in figure 6.45. The interaction term is statistically significant but the moderation figure resembles a main effect because there was no negative coping X perceived social support interaction (Cohen and Wills, 1985).

Table 6.20 Mr F: Negative coping $_{(log)}$ and negative affect $_{(log)}$ moderated by perceived social support

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	2.103	0.083			
Z score negative coping $_{(log)}$	0.196*	0.093*	0.254*		
Z score perceived support	0.019	0.093	0.024	0.087**	0.063**
Step 2					
Constant	2.034	0.083			
Z score negative coping $_{(log)}$	0.282*	0.095*	0.367*		
Z score perceived support	0.397*	0.166*	0.516*		
Z score negative coping $_{(log)}$ X Z score perceived support	0.150**	0.055**	0.619**	0.153**	0.119**

Dependant variable negative affect $_{(log)}$ *p<0.05, **p<0.01, n=78

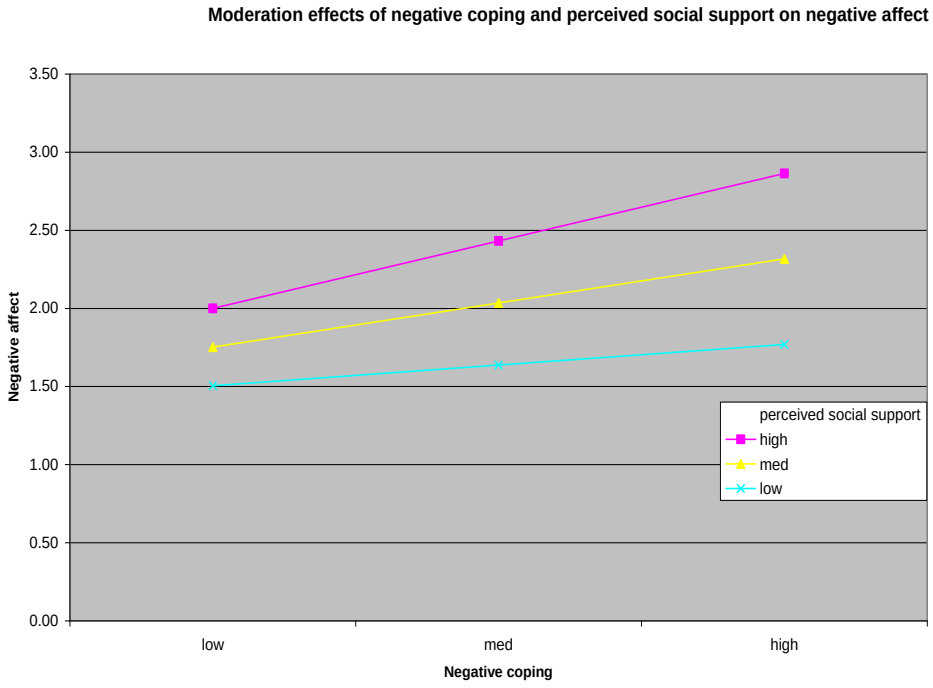


Figure 6.45 Mr F: Negative coping $_{(log)}$ and negative affect $_{(log)}$ moderated by perceived social support

Mr G (locally advanced prostate cancer – hormone therapy and radiotherapy)

For Mr G, negative coping $_{(preW\ lag\ 1)}$ and square root received social support $_{(preW\ lag\ 1)}$ (at the P<0.15) were associated to square root negative affect $_{(preW\ lag\ 1)}$. No associations were found with positive coping or perceived social support with square root negative affect $_{(preW\ lag\ 1)}$ and therefore, the analyses were performed with negative coping and received social support only. No main or moderations effects were found see table 6.21.

Table 6.21 Mr G: Negative coping $_{(preW\ lag\ 1)}$ and square root negative affect $_{(preW\ lag\ 1)}$ moderated by square root received social support $_{(preW\ lag\ 1)}$

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	4.406	0.127			
Z score negative coping $_{(preW\ 1)}$	0.235	0.129	0.186		
Z score received support $_{(preW\ 1)}$	0.181	0.129	0.143	0.059	0.039
Step 2					
Constant	4.402	0.129			
Z score negative coping $_{(preW\ 1)}$	0.234	0.129	0.185		
Z score received support $_{(preW\ 1)}$	0.185	0.130	0.146		
Z score negative coping $_{(preW\ 1)}$ X Z score received support $_{(preW\ 1)}$	0.045	0.129	0.036	0.061	0.030

Dependant variables square root negative affect $_{(preW\ lag\ 1)}$ *p<0.05, **p<0.01, n=92

Mr H (locally advanced prostate cancer – hormone therapy and radiotherapy)

Positive coping (r=-0.278, P<0.01), negative coping (r=0.331, P<0.01), perceived social support $_{(preW\ lag\ 1)}$ (r=-0.266, P<0.05) and received social support $_{(preW\ 1)}$ (r=0.184, P=0.083 at the P<0.15 level) was associated with negative affect $_{(preW\ lag\ 1)}$. Received social support $_{(preW\ 1)}$ and perceived social support $_{(preW\ 1)}$ did not moderate the relationship between positive coping and negative affect (see tables 6.22 and 6.23). In addition, received and perceived social support did not moderate the relationship between negative coping and negative affect (see table 6.24 and 6.25). Main effects were found for positive coping, negative coping and perceived social support $_{(preW\ 1)}$ on negative effect.

Table 6.22 Mr H: Positive coping and negative affect $_{(preW\ lag\ 1)}$ moderated by received social support

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	-0.050	1.373			
Z score positive coping	-3.790**	1.384**	-0.277		
Z score received support $_{(preW\ 1)}$	2.478	1.381	0.182	0.110**	0.090
Step 2					
Constant	-0.055	1.379			
Z score positive coping	-3.761**	1.391**	-0.275**		
Z score received support $_{(preW\ 1)}$	2.473	1.386	0.181		
Z score positive coping X Z score received support $_{(preW\ 1)}$	-0.625	1.188	-0.053	0.113	0.082

Dependant variable negative affect $_{(preW\ lag\ 1)}$ *p<0.05, **p<0.01, n=90

Table 6.23 Mr H: Positive coping and negative affect $_{(preW\ lag\ 1)}$ moderated by perceived social support $_{(preW\ lag\ 1)}$

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	-0.041	1.368			
Z score positive coping	-3.057*	1.430*	-0.223*		
Z score perceived support $_{(preW\ 1)}$	-2.819*	1.427*	-0.207*	0.117**	0.097**
Step 2					
Constant	0.159	1.434			
Z score positive coping	-3.457*	1.654*	-0.253*		
Z score perceived support$_{(preW\ 1)}$	-2.738	1.443	-0.201		
Z score positive coping X Z score perceived support $_{(preW\ 1)}$	-0.781	1.600	-0.057	0.120**	0.089**

Dependant variable negative affect $_{(preW\ lag\ 1)}$ *p<0.05, **p<0.01, n=90

Table 6.24 Mr H: Negative coping and negative affect $_{(preW\ lag\ 1)}$ moderated by perceived social support $_{(preW\ lag\ 1)}$

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	-0.096	1.341			
Z score negative coping	4.045**	1.404**	0.290		
Z score perceived support $_{(preW\ 1)}$	-2.850*	1.375*	-0.209	0.152**	0.132**
Step 2					
Constant	-0.339	1.366			
Z score negative coping	4.165**	1.410**	0.299**		
Z score perceived support$_{(preW\ 1)}$	-3.278*	1.488*	-0.240		
Z score negative coping X Z score perceived support $_{(preW\ 1)}$	-1.259	1.327	-0.100	0.161**	0.131**

Dependant variable negative affect $_{(preW\ lag\ 1)}$ *p<0.05, **p<0.01, n=90

Table 6.25 Mr H: Negative coping and negative affect $_{(preW\ lag\ 1)}$ moderated by received social support $_{(preW\ 1)}$

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	-0.102	1.361			
Z score negative coping	4.298**	1.420**	0.308**		
Z score received support $_{(preW\ 1)}$	1.754	1.391	0.128	0.152**	0.132**
Step 2					
Constant	-0.296	1.389			
Z score negative coping	4.234**	1.426**	0.304**		
Z score received support$_{(preW\ 1)}$	1.674	1.399	0.123		
Z score negative coping X Z score received support $_{(preW\ 1)}$	1.130	1.503	0.076	0.161**	0.131**

Dependant variable negative affect $_{(preW\ lag\ 1)}$ *p<0.05, **p<0.01, n=90

Mr I (locally advanced prostate cancer – hormone therapy and radiotherapy)

Positive coping and square root received social support $_{(preW\ lag\ 2)}$ was not associated with negative affect $_{square\ root}$. Negative coping $_{(preW\ lag\ 1)}$ and square root perceived social support $_{(preW\ lag\ 2)}$ was associated with negative affect $_{square\ root}$ at the p<0.15 level. The analysis was only performed with negative coping and perceived social support only. No moderation or main effects were found for Mr I (see table 6.26).

Table 6.26 Mr I: Negative coping $_{(preW\ lag\ 1)}$ and negative affect $_{(square\ root)}$ moderated by square root perceived social support $_{(preW\ lag\ 2)}$

Step and variable	B	SE B	β	R^2	Adj R^2
Step 1					
Constant	4.216	0.063			
Z score negative coping $_{(preW\ 1)}$	0.053	0.068			
Z score perceived support $_{(preW\ 2)}$	-0.101	0.064	-0.183	0.045	0.018
Step 2					
Constant	4.226	0.063			
Z score negative coping $_{(preW\ 1)}$	0.046	0.067	0.079		
Z score perceived support$_{(preW\ 2)}$	-0.081	0.065	-0.147		
Z score negative coping $_{(preW\ 1)}$ X Z score perceived support $_{(preW\ 2)}$	-0.095	0.070	0.160	0.070	0.030

Dependant variable negative affect $_{(square\ root)}$ *p<0.05, **p<0.01, n=74

Mr J (metastatic cancer – hormone therapy)

Positive coping $_{(PreW\ lag\ 1)}$ (r=0.297, P<0.01) and square root negative coping $_{(PreW\ lag\ 1)}$ (at the p<0.15 level) was associated with negative affect $_{(preW\ lag\ 1)}$. Perceived and received social support did not have any associations with negative affect $_{(preW\ lag\ 1)}$ and therefore, the analyses were not performed because the conditions were not met.

Mr K (metastatic cancer – hormone therapy)

Perceived social support $_{(preW\ lag\ 1)}$ (r=0.223, P<0.05) was significantly related to negative affect $_{(preW\ lag\ 1).}$ Positive coping $_{(preW\ lag\ 1)}$ and square root negative coping $_{(preW\ lag\ 1)}$ was unrelated to negative affect. Therefore, the analyses were not performed because of the non-association with the independent variables.

MEDIATION

Building upon the moderation analyses, mediation analyses were undertaken to establish whether social support (perceived and received) mediates the relationship between coping (positive and negative) and negative affect (see figure 6.46).

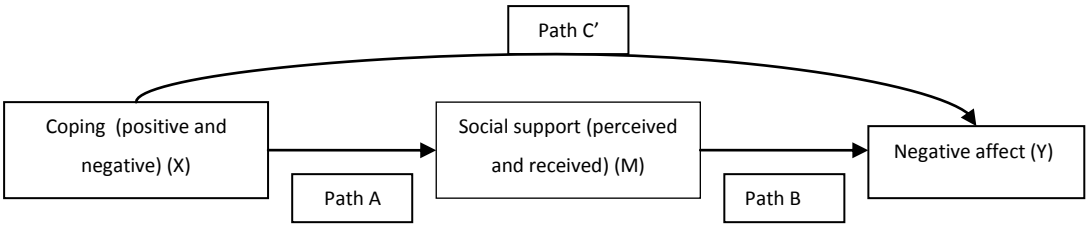


Figure 6.46 Mediation model

Mr A (localised prostate cancer – active surveillance)

Perceived social support partially mediated the relationship between negative coping $_{square\ root}$ and negative affect $_{square\ root}$ (see table 6.27), the beta weight reduced from 0.299 (path c) to 0.197 (path c') when controlling for perceived social support. The other conditions for mediation were met (see figure 47) and the Sobel's test found that the mediation effect was significant (Z=2.11, P<0.05). Using the bootstrapping procedure, similar results were obtained and at the 95% confidence interval the indirect effect coefficient did not cross zero (point estimate =0.0315 LL, 0.2390 UL).

Table 6.27 Mr A: Negative coping $_{\text{square root}}$ and negative affect $_{\text{square root}}$ partially mediated by perceived social support

Step and variable	B	SE B	β	R^2
Step 1 (path C)				
Constant	1.844	0.392		
Outcome: SQRT Negative affect				
Predictor: SQRT Negative coping	0.324**	0.111	0.299**	0.089
Step 2 (Path A)				
Constant	6.233	1.867		
Outcome: Perceived social support				
Predictor: SQRT Negative coping	-1.411**	0.531	-0.276**	0.076
Step 3 (path b and c')				
Constant	9.387	2.066		
Outcome: SQRT Negative affect				
Mediator: Perceived social support (path b)	-0.078***	0.021	-0.371***	
Predictor: SQRT Negative coping	0.213*	0.108	0.197*	0.216

*P<0.05, **P<0.01, P<0.001, n=88

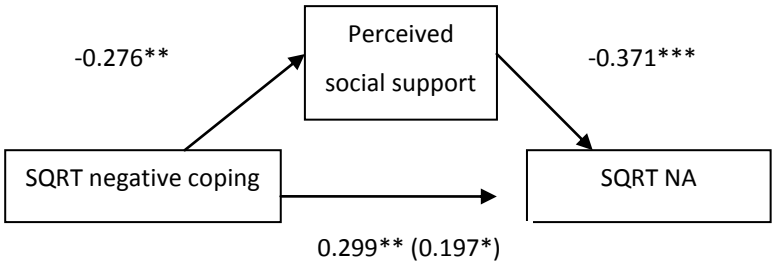


Figure 6.47 Beta weights for the relationship between SQRT negative coping and SQRT NA partially mediated by perceived social support for Mr A.

The beta weights for SQRT negative coping and SQRT NA controlling for perceived social support are in the parentheses *P<0.05, **P<0.01, ***P<0.001

Perceived social support also partially mediated the relationship between positive coping and negative affect $_{\text{square root}}$ (see table 6.28); the beta weight reduced from -0.419 (path c) to -0.286 (path c') when controlling for perceived social support. The other conditions for mediation were met (see figure 48) and the Sobel's test found that the mediation effect was significant (Z=-2.36, P<0.05). Using the bootstrapping procedure, similar results were obtained and at the 95% confidence interval the indirect effect coefficient did not cross zero (point estimate = -.0455 LL, -.0090 UL).

Table 6.28 Mr A: Positive coping and negative affect $_{\text{square root}}$ partially mediated by perceived social support

Step and variable	B	SE B	β	R^2
Step 1 (path C)				
Constant	10.372	1.736		
Outcome: SQRT negative affect				
Predictor: Positive coping	-0.082***	0.019	-0.419***	0.175
Step 2 (Path A)				
Constant	53.968	8.084		
Outcome: Perceived social support				
Predictor: Positive coping	0.411***	0.089	0.447***	0.200
Step 3 (path b and c')				
Constant	13.761	2.058		
Outcome: SQRT Negative affect				
Mediator: Perceived social support (path b)	-0.063**	0.022	-0.297**	
Predictor: Positive coping	-0.056**	0.020	-0.286**	0.246

*P<0.05, **P<0.01, P<0.001, n=88

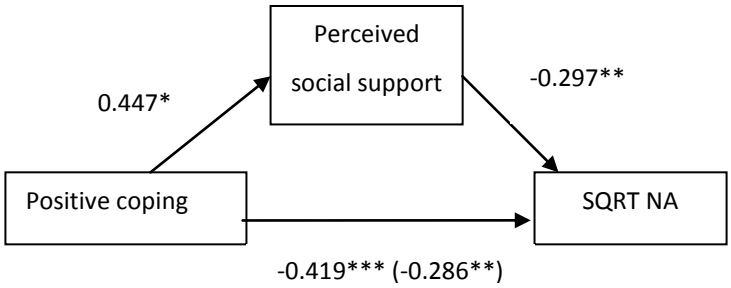


Figure 6.48 Beta weights for the relationship between positive coping and SQRT NA partially mediated by perceived social support for Mr A

The beta weights for positive coping and SQRT NA controlling for perceived social support are in the parentheses *P<0.05, **P<0.01, ***P<0.001

Mediation was not possible for Mr B, Mr C, Mr D, Mr E, Mr F, Mr G or Mr I because the conditions for mediation were not met.

Mr H (locally advanced prostate cancer – hormone therapy and radiotherapy)

Received social support $_{(\text{preW lag 1})}$ did not mediate the relationship between positive coping/negative coping and negative affect $_{(\text{preW lag 1}),}$ because the conditions were not met. Perceived social support $_{(\text{preW lag 1})}$ partially mediated the relationship between positive coping and negative affect $_{(\text{preW lag 1})}$ because the beta weight dropped from -0.278, P<0.01 to -0.233, P<0.05 and all the conditions for mediation were met (see

table 6.29 and figure 6.49). However, the Sobel's test was non-significant Z=-1.502, P=0.1331 and when using the bootstrapping procedure similar results were obtained (point estimate = -0.3128 LL, 0.0213 UL). Therefore, perceived social support $_{(preW\ lag\ 1)}$ did not partially mediate the relationship between positive coping and negative affect $_{(preW\ lag\ 1)}$.

Table 6.29 Mr H: Positive coping and negative affect $_{(preW\ lag1)}$ partially mediated by perceived social support $_{(preW\ lag1)}$

Step and variable	B	SE B	β	R^2
Step 1 (path C)				
Constant	52.413	19.329		
Outcome: Negative affect $_{(preW\ lag1)}$				
Predictor: Positive coping	-0.582**	0.214	-0.278**	0.077
Step 2 (Path A)				
Constant	-65.317	25.272		
Outcome: Perceived social support$_{(preW\ lag1)}$				
Predictor: Positive coping	0.725*	0.280*	0.266*	0.071
Step 3 (path b and c')				
Constant	42.059	19.727		
Outcome: Negative affect $_{(preW\ lag1)}$				
Mediator: Perceived social support $_{(preWlag1)}$ (path b)	-0.159*	0.080	-0.207*	
Predictor: Positive coping	-0.467*	0.218	-0.223*	0.117

*P<0.05, **P<0.01, P<0.001, n=88

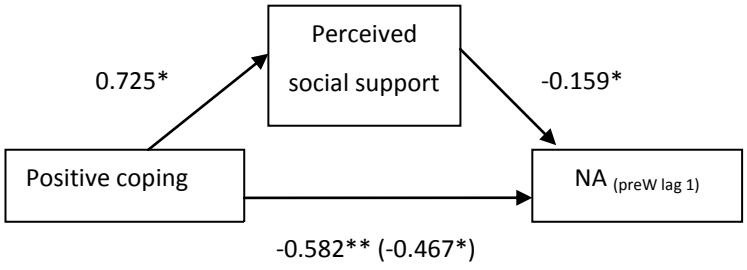


Figure 6.49 Beta weights for the relationship between positive coping and SQRT NA partially mediated by perceived social support for Mr H.

The beta weights for positive coping and SQRT NA controlling for perceived social support are in the parentheses *P<0.05, **P<0.01, ***P<0.001

A second mediation analysis was performed with negative coping and negative affect mediated by perceived social support (see table 6.30 and figure 6.50). The conditions for mediation were met for mediation but the Sobel's test (Z=1.31, P=0.1888) was

non-significant and the zero was in the 95% confidence interval (CI) bootstrapped sample (lower limit 95% CI -0.0072, upper limit CI 0.1769) therefore, partial mediation was not present.

Table 6.30 Mr H: Negative coping and negative affect $_{(preW\ lag1)}$ partially mediated by perceived social support $_{(preW\ lag1)}$

Step and variable	B	SE B	β	R^2
Step 1 (path C)				
Constant	-13.253	4.247		
Outcome: Negative affect $_{(PreW\ lag\ 1)}$				
Predictor: Negative coping	0.441**	0.134**	0.331**	0.110**
Step 2 (Path A)				
Constant	10.272	5.750		
Outcome: Perceived social support $_{(PreW\ lag\ 1)}$				
Predictor: Negative coping	-0.181	-0.197	0.039	0.079
Step 3 (path b and c')				
Constant	-11.607	4.245		
Outcome: Negative affect $_{(PreW\ lag\ 1)}$				
Mediator: Perceived social support $_{(PreW\ lag\ 1)}$) (path b)	-0.160*	0.077*	-0.209*	
Predictor: Negative coping	0.386**	0.134**	0.290**	0.152*

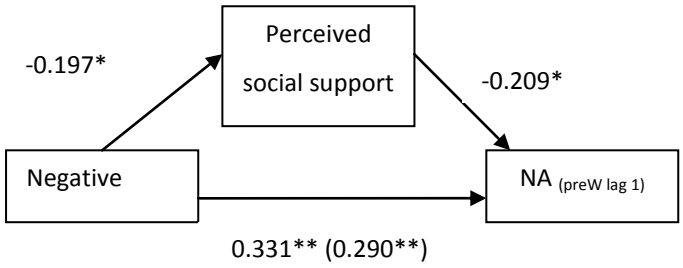


Figure 6.50 Beta weights for the relationship between positive coping and SQRT NA partially mediated mediated by perceived social support for Mr H.

The beta weights for positive coping and SQRT NA controlling for perceived social support are in the parentheses *P<0.05, **P<0.01, ***P<0.001

A summary of main, moderation and mediation effects across all of the eleven case studies are presented in table 6.31. In relation to the sampling framework, no pattern of results are identified for main, moderation and mediation effects for social support with cancer stage, level of social support and co-morbidity. No commonalities or differences are identified when comparing the variables in table 6.2 (section 6.5.3) for the following: socio-economic status, level of education, employment status, age or co-morbidity.

Table 6.31 Summary of main, moderation and mediation effects across the eleven case studies

Sampling framework criteria)	Main effects	Moderation effects	Mediation effects
Mr A (localised cancer/high support)	Positive coping Negative coping Perceived social support	None	Yes – negative coping and negative affect is partially mediated by perceived social support. Positive coping and negative affect is partially mediated by perceived social support
Mr B (localised cancer/low support)	Positive coping Received social support	Yes – high positive coping is associated with high negative affect under conditions of high received social support. Low negative coping is associated with high negative affect when received social support is low.	None
Mr C (localised cancer/high support)	Positive coping Negative coping	Yes – low negative coping is associated with high negative affect under conditions of low received social support.	None
Mr D (localised cancer/high support)	None	None	None
Mr E (locally advanced cancer/high support)	None	None	None
Mr F (locally advanced cancer/high support)	Negative coping	Yes – High negative coping was associated with high negative affect under conditions of low received social support. High negative coping is associated with high negative affect under conditions of high perceived social support	None
Mr G (locally advanced cancer/low support)	None	None	None
Mr H (locally advanced cancer/high support)	Negative coping Positive coping Perceived social support	None	Conditions for mediation met - negative coping and negative affect partially mediated by perceived social support. Positive coping and negative affect is partially mediated by perceived social support. But Sobel's test and bootstrapping results were non-significant, thus mediation not present.
Mr I (locally advanced cancer/low support)	None	None	None
Mr J (metastatic cancer/low support)	None	None	None
Mr K (metastatic cancer/high support)	None	None	None

6.6 N-of-1 Discussion

Each single-case study will be discussed separately followed by a general discussion across the 11 case studies. The limitations of the diary methodology will be acknowledged in the general discussion.

Mr A (Localised Prostate Cancer, Active Surveillance, High Support)

Mr A was a married, 73-year-old gentleman with localised prostate cancer undergoing the active surveillance programme. The electronic diary was well accepted by Mr A and he demonstrated a good compliance rate of 94.6%. Coping and perceived availability of social support both demonstrated a main effect on emotional outcome and provided support for the main effect theoretical model (Cohen and Wills, 1985) because perceived social support significantly reduced negative affect for Mr A. This significant result demonstrates that the main effects model (Cohen and Wills, 1985) holds within-person design. Mediation effects were also identified for perceived social support whereby coping was related to negative affect partially because of perceived social support. Mr A's results have enabled a stronger theoretical grasp of the mechanism effect through which social support operates by the identification of a mediating pathway. The findings did not support the buffering model and received social support did not have any associations with coping or negative affect. For Mr A, perceived social support was the most important predictor of emotional outcome. This finding is in keeping with (Zhou et al., 2010a, Roberts et al., 2006) and with the findings in chapter 5 (prospective longitudinal study), albeit average group level findings.

Although Mr A did not receive treatment for his prostate cancer, he still frequently experienced urinary symptoms over the one-month period of data collection and performed urinary self-management on five occasions. Unfortunately, Mr A did not detail his urinary self-management strategies but reported good symptom relief from these. Mr A's self-report of urinary dysfunction is in keeping with existing published data (Thong et al., 2009, Hoffman et al., 2006) which has identified men undergoing active surveillance reported urinary dysfunction. Mr A did not report any additional self-management behaviours however, he experienced the following symptoms: impotence, tiredness and constipation but he did not perform self-management

behaviours to relieve these symptoms. It is unclear as to why Mr A did not report self-management behaviours to relieve his symptoms, but there are a few possible explanations.

One possible explanation is around self-care self-efficacy, which is a construct that refers to an individual's confidence in their actions and beliefs about performing their self-management behaviours. Low self-efficacy has been linked to patients' withdrawal of participation in self-management because they believe that they cannot influence the outcome regardless of their ability (Cockle-Hearne and Faithfull, 2010). However, in the case of Mr A, this would seem an unlikely explanation because his self-care self-efficacy was very high 92.7 (SD 3.2) (0-100 scale).

Alternatively, it is possible that, although Mr A experienced impotence, constipation and tiredness, he may not have been bothered by his symptoms and therefore, did not feel the need to perform self-management. It is identified that people with cancer who view their symptoms as "normal" are not bothered by them and consequently, people do not seek health care for symptom relief (O'Rourke, 2007). This man may have viewed his symptoms as normal due to increasing age and the effects of his cancer, and, as such, was not bothered by them. This study did not have a measurement of symptom bother or severity. Mr A did not perform self-management for his symptoms (impotence, constipation and tiredness) and it could be suggested that he was not bothered by them, but this will remain unknown. A final explanation could be that Mr A did not report self-management behaviours to relieve these symptoms, in particular, self-management for impotence, because he provided socially desirable responses (Lonnqvis et al., 2007) but this would seem unlikely because he reported that he experienced impotence.

In summary, the main effects theoretical model was supported within-person design and a mediating pathway was identified that linked coping to emotional outcome because of perceived availability of social support. This man performed urinary self-management with good relief, but no additional self-management behaviours were identified. Additional symptoms were experienced (impotence, constipation and tiredness) but no self-management behaviours were performed.

Mr B (Localised Prostate Cancer, Active Surveillance, Low Support)

In the case of Mr B, he was a married 61-year-old gentleman diagnosed with localised prostate cancer undergoing the active surveillance programme. Mr B demonstrated a good electronic diary compliance rate of 90.3%. Positive coping and received social support both demonstrated a main effect on emotional outcome for Mr B. However, the propositions of the main effects theoretical model (Cohen et al., 2000, Cohen and Wills, 1985, Cohen and McKay, 1984) were not supported because received social support (β=.264, $p<.05$) predicted an increase in negative effect. This is a paradoxical result. The main effect model has the underlying assumption social support transactions are related to successful adaption for individuals and linked improved health outcomes. For Mr B, received social support did not have a favourable relationship on improved emotional outcome; quite the reverse, received social support significantly predicted greater emotional distress.

This result is in keeping with findings that have demonstrated receiving social support is associated with negative health outcomes for some individuals (Scholz et al., 2008, Schwarzer et al., 2006). There are a number of possible explanations to account for the negative effect of the receipt of social support for Mr B. One possible explanation is that Mr B's receipt of social support was mismatched to his "need for support". Some individuals produce better coping efforts and coping styles when one masters challenges alone, without help from others, and will only resort to receipt of assistance in the worst circumstances (Schwarzer and Knoll, 2007). For Mr B, the negative effect of social support provision may have reduced his autonomy and caused him to feel incapable of self-managing his condition. Furthermore, Mr B reported a reduced level of satisfaction with his social support (61.1, SD 18.5, 0-100 scale) over time which would be in keeping with this explanation. Although these data cannot confirm that Mr B's receipt of social support was mismatched to his needs, additional research would be important to match the provision of support and the needs of the support receiver within-person design. The stress and coping matching hypothesis (Cohen and McKay, 1984, Cutrona, 1990) posits that the type of social support matches the demands of the stressor, which promotes coping efforts and reduced the demands on the individual. For example, having someone lend you financial resources may be helpful during a time of temporary job loss, but would be useless during the bereavement of a loved one. For Mr B, it is possible that his

received social support provision was mismatched to his needs which could explain a) his lack of satisfaction with his social support, and b) the increases in negative affect. It is possible that individuals may also misperceive and under-report the amount of support they believe they receive. Negative affect can cloud perceptions of helpful acts or undermine beliefs about how much others care. Future work incorporating a didactic perspective may help to understand patients' and partners' experiences of support provision exchange, and would appear to be a worthwhile step to advance knowledge in this area.

Perceived social support did not significantly predict emotional outcome of Mr B. Relationships between the stress and coping process are complex and multivariate, and the research question was constrained to testing coping, social support on emotional outcome through exploring main, moderating and mediating pathways. Perceptions of availability of social support are believed to lead to appraising potentially threatening situations less stressful (Cohen et al., 2000). Mr B reported moderate perceived social support overtime (71.2, SD 22.6, 0-100 scale). It is possible for Mr B, his perceptions of his availability of social support facilitated positive coping efforts by appraising stressful situations less harmful for him, but this cannot be confirmed within the current study. Additional work in this area may clarify how appraisal and additional variables such as demand, control and self-efficacy are linked to social support processes and health in men affected by prostate cancer.

Mr B performed urinary self-management every day throughout his one-month period of data collection. His urinary self-management was limited to taking only medication and his urinary symptoms did not display a trend of improvement over time. It could be speculated that additional self-management behaviours may have improved Mr B's symptom relief, but this would remain unknown. Mr B had high self-care self-efficacy and, therefore, it is likely that he found his self-management easy and he felt confident in his ability to self-manage. But Mr B reported low perceived social support and reduced satisfaction levels with social support over time. It is possible that Mr B may have experienced a lack of awareness of available support to help with his self-management of his urinary symptoms and this has been acknowledged in a fairly recent publication (Ream et al., 2008) for men affected by prostate cancer.

In summary, received social support was found to predict greater emotional distress for Mr B. The main effects model and the stress buffering model did not hold within-person design. This case study had identified the negative effects of social support on health outcomes and suggests that stress and coping matching hypothesis would be worthy of further research. Mr B frequently experienced urinary symptoms, but only performed one incident of self-management behaviour with little relief.

Mr C (Localised Prostate Cancer, Laparoscopic Radical Prostatectomy, High Support)

Mr C was a married, 51-year-old gentleman with localised prostate cancer and was treated by a laparoscopic prostatectomy. The electronic diary was well accepted by Mr A and he demonstrated a good diary completion rate of 87%. Negative coping and positive coping predicted negative affect. However, the social support variables (perceived and received social support) had no relationship with emotional outcome. Mr C reported high perceived social support with an overall high level of satisfaction with his social support but were unrelated with emotional outcome. This result does not fit with existing aggregate group level effects linking perceptions of social support to improved health outcomes for men affected by prostate cancer (Zhou et al., 2010a, Roberts et al., 2006, Rondorf-Klym and Colling, 2003). The non-association with perceived social support and negative affect is unclear. Thus for Mr C, perceived social support was not linked to improved health outcomes, but a significant moderation effect was identified. Low negative coping was association with high negative affect under conditions of low received social support. Interestingly, Mr C reported high availability of social support meaning that he anticipated receiving a high level of social support in times of need. These findings suggest that Mr C was unable to mobilise his receipt of social support when he needed it. Additional work is needed that will incorporate a dyadic perspective on social support exchange for men affected by prostate cancer and support providers. This approach may provide valuable insights into how men self-manage at the individual level.

Mr C performed urinary self-management every day over the course of one month to relieve urinary incontinence, urinary urgency and urinary frequency. He performed nine urinary self-management behaviours with a trend of symptom relief over time. Based on the number of times self-management was performed and the variety of

strategies used by Mr C, this result would suggest that Mr C may have been bothered by his symptoms. Elsewhere it has been identified that urinary dysfunction after surgery has been reported as the most bothersome symptom (Weber et al., 2008) compared to sexual and bowel bother. Mr C may have been bothered by his urinary symptoms and performed self-management behaviours to reduce the degree of annoyance, dysfunction and discomfort of his symptoms, but this will remain unknown.

Bowel symptoms were less frequently experienced over time by Mr C and this is in keeping with existing research (Sanda et al., 2008, Shrader-Bogen et al., 1997) for men treated by surgery. Bowel dysfunction is less common in men treated by radical prostatectomy, compared to urinary and sexual dysfunction. Mr C frequently experienced erectile dysfunction over time but he performed self-management only on one occasion. It is possible that sexual bother was not experienced by Mr C at this point in his recovery (1 month following surgery) and therefore, performing self-management for sexual potency was not as important as urinary self-management at this stage in his recovery. It is possible Mr C may perform sexual function self-management over time as he adjusts to living with erectile dysfunction (Nelson et al., 2011) because sexual bother has been identified at one year post-surgery (Gacci et al., 2005). Ultimately, this will remain unknown for Mr C.

In summary, the main effects model did not hold within-person design but a significant moderation effect was identified. High negative coping was associated with high negative affect under conditions of low received social support. This suggests that Mr C was not able to mobilise his social support when he needed it or that the support he received was not matched to his needs. Mr C performed urinary self-management every day throughout the course of the month and there was a trend of improved symptoms over time. Based on the frequency and variety of urinary self-management it is possible that urinary dysfunction was the most bothersome after effect of surgery for Mr C. Bowel and sexual function self-management were less frequently performed over time but recognising that sexual function self-management frequency may change as Mr C adjusts to living with erectile dysfunction.

Mr D (Localised Prostate Cancer, Laparoscopic Radical Prostatectomy, High Support)

In the case of Mr D, he was a married 59-year-old man with localised prostate cancer and treated by laparoscopic radical prostatectomy. The diary was well accepted and he had a good diary response rate (97.7%). Negative coping, positive coping, received and perceived social support did not have any associations with negative affect and therefore, the main effects model and the buffering hypothesis did not hold within-person design. The non-association among the variables may have been supressed because of the little variance displayed in negative affect. The theoretical relationship between social support and health is well established, albeit in group-based studies. The theoretical models did not apply to Mr D at the individual person experience.

Other variables may have predicted negative affect for Mr D that were not explored because the research question aimed to test coping and social support on negative affect which was underpinned by the social support theories. The social support theories have not been tested within-person design before and therefore, data only support group-based studies, between-participant studies and are limited to average effects. Despite the prominence of testing theory on group-level studies, it is assumed that the theory will apply to individuals (Molenaar, 2004). One explanation is that the constructs may operate differently over time when applied to individuals and this seems a likely explanation, because Mr B identified negative consequences of social support on health, and, for Mr D, no associations were identified.

Mr D performed urinary self-management every day and reported good relief from his self-management behaviours, similar to that of Mr C. He performed two urinary self-management behaviours, whereas Mr C (who received the same treatment as Mr D) performed nine urinary self-management behaviours. The increased variety of self-management behaviours performed by Mr C, compared to Mr D, could be explained by urinary symptoms. Mr C experienced more urinary symptoms compared to Mr D over time and therefore, Mr C's increased urinary dysfunction may account for this. Bowel symptoms and impotence were infrequently experienced by Mr D and he did not perform bowel and sexual function self-management. Mr C reported impotence very frequently throughout the one-month

period, which was dissimilar to Mr D. It is likely however, that Mr D was impotent at this stage in his recovery due to nerve damage following surgery (Kouba et al., 2007, Ball et al., 2006, Namiki et al., 2004) but did not report impotence. It may be that Mr D did not experience impotence because he was not sexually aroused over the one-month period of data collection. Thus he did not report impotence. Alternatively, it is also possible that Mr D did not report impotence because he provided socially desirable responses (Lonnqvis et al., 2007) because he was embarrassed, but this will remain unknown.

Additional self-management behaviours were performed for an infected surgical wound and for ankle oedema. Mr D performed four self-management behaviours for his wound management and three self-management behaviours for his ankle oedema. These were complications following Mr D's surgery that Mr C did not experience. Mr D performed wound self-management almost every day and his self-management behaviours included the following: dressed the wound, sought help from nurse and doctor, changed and emptied wound drainage bag and took antibiotics. Is seems that Mr D was able to mobilise his support (help from healthcare professionals) to assist him to self-management his wound infection.

In summary, the results show no relationship between coping and social support on emotional outcome for Mr D. Mr D performed self-management for 3 problems/symptoms following his treatment and these included: urinary symptoms, wound infection and ankle oedema. Based on the frequency of Mr D's self-management behaviours it is possible that urinary dysfunction and his wound infection were most bothersome for him at this point in his cancer trajectory.

Mr E (Locally Advanced Cancer, Neoadjuvant Hormone Therapy and Radiotherapy, High Support)

Mr E was a 65-year-old married man with high social support. This man was diagnosed with locally advanced prostate cancer and was treated with neoadjuvant hormone therapy and radiotherapy. The diary was well accepted and he had a good diary response rate of 97.9%. For Mr E, negative affect did not have any associations with coping variables or perceived social support. The propositions of the social

support theories were not supported by Mr E. These results are similar to Mr D's, because both men's (Mr E and Mr D) data did not empirically support the theoretical models of social support. The reason as to why the theoretical models did not apply to Mr E and Mr D are unclear, but will be explored over the course of the emerging discussion.

Mr E performed bowel self-management only on three days with good relief. He took medication as his only self-management behaviour. Interestingly, there was a lag between his bowel self-management and his diarrhoea which suggested Mr E may have performed self-management as prevention, rather than a cure. No other self-management behaviours were reported, but Mr E frequently experienced impotence and urinary symptoms over time. It is possible that Mr E did not perform urinary and sexual function self-management for his symptoms for a number of reasons. This man was dissatisfied with his social support and therefore, it is possible that he did not have access to appropriate informational or practical support that was personalised to his needs to help him to self-manage his symptoms. However, he reported high self-care self-efficacy and therefore, it would seem likely that Mr E had ease and confidence in his ability to manage his symptoms. This leads to an alternative explanation related to symptom bother. Using the frequency of self-management behaviours as a proxy measure for symptom bother (but recognising the limitations of this), it is possible that his impotence and urinary symptoms did not cause him annoyance or discomfort. This seems a likely explanation because over time, Mr E reported low scores of negative affect scores. Similarly, Mr A experienced sexual dysfunction but he did not report sexual function self-management behaviours to relief his impotence. It is possible that both Mr A and Mr E viewed their symptoms as "normal" and consequently, they did not seek health care for symptom relief (O'Rourke, 2007). Impotence is a common side effect of hormone therapy because this type of therapy stops testosterone production (Cancer Research UK, 2011). Mr E may have adjusted to living the side effects of his treatment, and this was not significantly impacting on his quality of life because he reported very high quality of life scores (99.2, SD 11.2, 0-100 scale). However, the impact of his urinary and sexual dysfunction has the potential to become bothersome and affect his quality of life at a later stage in his survivorship journey, but this will remain unknown.

In summary, the propositions of the social support theories were not supported by Mr E's results. Mr E performed self-management for diarrhoea and no additional self-management behaviours were identified. Impotence and urinary symptoms were experienced but no self-management was performed.

Mr F (Locally Advanced Cancer, Neoadjuvant Hormone Therapy and Radiotherapy, High Support)

This gentleman was 57-year-old married man who was diagnosed with locally advanced prostate cancer and was treated with hormone therapy and radiotherapy. For Mr F, negative coping had a main effect on negative affect, but positive coping had no association with the dependent variable. Similarly, received and perceived social support did not have a main effect and therefore, these results do not support the main effects theoretical model. A significant moderating effect was identified for received social support. The results identified that high negative coping was associated with high negative affect under conditions of low received social support. This finding was similar to Mr C who was diagnosed with localised prostate cancer and treated by surgery.

Interestingly, Mr F reported high perceived availability of social support with very little variance over time. This suggests that although Mr F had high perceptions of availability of social support at a time of need, his actual receipt of social support may not have been matched to his support needs over time. One possible explanation could be related to Mr F's stage of his cancer journey. Potentially, his social network may have withdrawn their social support unconsciously/consciously because Mr F had passed the acute phase of the cancer continuum (diagnosis and treatment). This is a probable explanation and a similar finding has been reported elsewhere (Visser et al., 2003).

A second moderating effect was identified for Mr F and the results indicate that high negative coping is associated with high negative affect under conditions of high perceived social support. This is a paradoxical finding and does not support the propositions of the social support theories. Existing social support theories postulates that perceptions of perceived social support will influence the appraisal of stressful encounters and will therefore, increase coping efforts. For Mr F, the

interaction term was statistically significant, but the moderation figure resembled a main effect because there was no coping X social support interaction pattern (Cohen and Wills, 1985) (figure 6.42). It maybe that Mr F's negative coping is associated with negative affect regardless of the level of perceived availability of social support. Mr F may have become accustomed to high perceived social support over time with little variance. This may suggest that when Mr F coped negatively his perceptions of his social support did not have a protective effect in reducing psychological distress over time. It maybe that low received social support is more likely to influence negative coping and negative affect than perceived social support.

Urinary symptoms were frequently experienced over time and Mr F performed four urinary self-management behaviours over time with good relief. Mr E had the same cancer stage and was treated by the same treatment modality as Mr F, but Mr F did not experienced urinary symptoms. The difference in the symptoms profiles of these two men could be explained by the toxicities caused by treatment (Fonteyne et al., 2009) that were experienced by Mr F and not Mr E. Mr F frequently experienced diarrhoea and performed two self-management strategies with good relief. Similarly, both men (Mr F and Mr E) identified a lag between self-management and bowel symptoms and this result would suggest that self-management was performed for prevention and also cure. No additional self-management was reported by Mr F, however, Mr F frequently experienced impotence over time but no self-management was reported. This finding has also been identified for Mr A and Mr E and so far, several explanations have been identified, but this commonality will be explored further in the general discussion.

In summary, negative coping was associated with negative affect under conditions of low received social support. Mr F performed urinary and bowel self-management for symptoms over time. Furthermore, impotence was a frequently experienced symptom but no self-management was reported.

Mr G (Locally Advanced Cancer, Neoadjuvant Hormone Therapy and Radiotherapy, Low Support)

Mr G was a married 64-year-old man with low social support. Coping and social support variables did not have any association with negative affect. These findings suggest that in situations experienced by Mr G, social support was not salient. The non-significant results suggest poor applicability of the social support theory in this case study. The findings do not support the social support theoretical models within-person design. This finding is similar to the results of Mr D and Mr E and therefore, the commonality of these findings will be further teased out in the general discussion. Specifically, for Mr G, he received very little social support over time and he was very dissatisfied with his social support. He also had low perceived social support over time. Surprisingly, received and perceived social support did not have any significant correlations with negative affect. According to social support theory, a negative correlation was anticipated between social support and negative affect. The emerging counter-theoretical relationships that have emerged across the three case studies (Mr G, Mr D and Mr E) may suggest that an intervention targeting social support would not be effective for these men, and demonstrates the need for a personalised approach and further work in this area.

Mr G frequently experienced urinary symptoms over time and performed self-management (four) behaviours every day. No trend of improved urinary symptoms or increased self-management relief was observed over time. Whereas, Mr F who had the same stage of cancer and received the same treatment as Mr G, displayed an obvious trend of improved urinary symptoms and good relief from his self-management over time, while Mr G did not. The difference in results between the two men could be related to the effects of treatment, but could also be related to social support. Mr F had high social support and mobilised his social support as a self-management behaviour for symptom relief, whereas Mr G reported low social support and did not use social support in his self-management. It could be that social support improved Mr F's coping efforts and was a resource to support his self-management. Interestingly, this emergent comparison was also identified between Mr A and Mr B. It might be considered that men who had high social support mobilised their support as self-management behaviour and improved symptom relief

was identified over time, whereas men with low social support did not use support as self-management behaviour and no obvious trend of symptom relief was identified. This is a tentative association but would be worthy of further research.

Mr G performed bowel self-management every day as a prevention and cure from constipation. This gentleman completed three incident entries related to his self-management of his bowel dysfunction. An example of one of his incidents included: "accidentally defecated into my underpants", this identifies the physical and psychological problems that men may experience following treatment for prostate cancer. Mr G did not seek support to help cope with his incident experiences. Bowel dysfunction is common following radiotherapy and therefore, the results of this case study are in keeping with existing studies (Berg et al., 2009, Fonteyne et al., 2009). Additional self-management was performed for problems with stress and sleeping problems. Noteworthy, none of the reviewed case studies (Mr A, Mr B, Mr C, Mr D, Mr E, Mr F) performed self-management for stress. The divergent self-management performed by Mr G is likely to be related to his pre-existing health problems of depression, asthma and hypertension. The six previously reviewed case studies did not have any pre-existing health problems. It is possible that Mr G's additional self-management was related to his pre-existing health problems.

In summary, the propositions of social support theory did not hold within-person for Mr G. This result is similar to that of My D and Mr E. In relation to the sampling framework criteria, the three men (Mr G, Mr D and Mr E) differed in clinical characteristics and level of social support. The reasons as to why social support and coping had no significant relationship with emotional outcome for these men will be addressed in the main discussion. Mr G performed self-management behaviours for bowel dysfunction every day and performed additional self-management for stress and sleeping problems.

Mr H (Locally Advanced Cancer, Neoadjuvant Hormone Therapy and Radiotherapy, High Support)

Mr H was a single man (no partner) who was 73 years of age. Positive and negative coping were found to have significant relationships with negative affect. Perceived

social support significantly predicted less negative affect and therefore, supports the main effects theoretical model (Cohen et al., 2000, Cohen and Wills, 1985, Cohen and McKay, 1984). No moderating or mediating pathways were identified for the social support constructs (perceived and received social support) between coping and emotional outcome. Received social support did not have any significant associations with negative affect, and suggests perceived social support was more relevant in predicting negative affect in the case study, and this finding was similar to Mr A. There were emerging commonalities for both these men because they were both 73 years old, had a high socio-economic status with high social support.

Mr H frequently experienced urinary symptoms and performed five urinary self-management behaviours with good relief; however, the frequency of urinary symptoms did not decrease over time. Bowel dysfunction was also experienced daily and he performed four bowel self-management behaviours. A commonality between Mr H's urinary and bowel self-management behaviours was that at approximately two weeks into Mr H's diary data collection, he stopped performing self-management for urinary and bowel dysfunction, but he continued to experience urinary and bowel dysfunction for the remaining 2 weeks of data collection. The reasons for Mr H discontinuing his self-management behaviours are unclear, but several possible explanations are considered. The measures used in this study did not assess symptom severity or symptoms bother and therefore, it is possible that Mr H was not bothered by his symptoms and, consequently, he did not take actions to relieve his symptoms. An alternative explanation could be related to low self-care self-efficacy, but this would appear to be an unlikely explanation because he had high self-care self-efficacy. This is a new emergent finding that has not been previously identified across the seven (Mr A, Mr B, Mr C, Mr D, Mr E, Mr F, Mr G) cases so far. In terms of clinical characteristics, Mr E, Mr F, and Mr G also had similar clinical characteristics to Mr H (locally advanced prostate cancer and were treated with neoadjuvant hormone therapy and radiotherapy), but this finding was only identified in this case study (Mr H). There was a spread of demographic characteristics within each of the cases and therefore, no obvious distinction can be made to explain Mr H discontinuing his self-management. The discontinuation of Mr H's urinary and bowel self-management could be related to his sexual function.

Sexual function self-management was frequently performed throughout the one-month period of data collection. Using the frequency of self-management behaviours as a proxy (but recognising the limitations of this approach) of symptom bother, Mr H may have had higher sexual function bother at this stage in his cancer journey compared to urinary and bowel bother. His data identifies that he continued his sexual function self-management, but discontinued his urinary and bowel self-management over time. This is a tentative assumption and therefore, should be treated with caution because, ultimately, this will remain unknown.

In summary, coping (positive and negative) and perceived social support significantly predicted negative affect and supports the propositions of the main effects theoretical model within-person design. Mr H experienced urinary, bowel and sexual dysfunction and performed a number of self-management behaviours with good relief. However, this gentleman continued to frequently experience urinary and bowel symptoms for which he did not perform self-management.

Mr I (Locally Advanced Cancer, Neoadjuvant Hormone Therapy and Radiotherapy, Low Support)

Mr I was a 73-year-old man, single and reported low social support. This gentleman was treated with neoadjuvant hormone therapy and radiotherapy for locally advanced prostate cancer. Coping (positive and negative) and social support variables did not have any significant relationship with negative affect. Consequently, the propositions of the social support theory did not hold for Mr I and this is similar to Mr D, Mr E and Mr G. Interestingly, the four men differed in terms of having a partner or not, level of social support and clinical characteristics, but these men were all retired and from a higher socio-economic background. The influence of being retired and from a higher socio-economic background is considered with caution because significant effects of social support have been identified with other participants with similar demographic characteristics (for example, Mr A, Mr B, and Mr H).

Urinary symptoms were experienced daily and Mr I performed six urinary self-management behaviours. No obvious trend of improved symptom relief was

achieved from self-management strategies for Mr I and this is similar to Mr B and Mr G. All three men (Mr B, Mr G and Mr I) had low social support and, therefore, for these men they may not have had access to the appropriate social support to help them to self-manage their symptoms, for example, informational or practical support. This is a tentative association which has been identified from the sampling framework and will be further considered in the general discussion.

Bowel self-management behaviours were performed daily for diarrhoea and this was similar to Mr F, Mr G and Mr H (all treated by radiotherapy). This commonality is in keeping with existing prospective data that identifies men can often experience bowel dysfunction following radiotherapy treatment (Berg et al., 2009, Namiki et al., 2006c) but this the first exploratory study which has identified actual self-management behaviours in this patient group. Mr I also reported erectile dysfunction daily and performed self-management for this on one occasion with little relief, and this finding was also identified for Mr C. The similarity of these findings may indicate that often men experience erectile dysfunction and attempt self-management but do not continue their behaviours over time. The reasons as to why men do not continue their sexual function self-management over time is worthy of further research to address any supportive care needs for this population.

In summary, the propositions of social support theory did not hold for Mr I (similar to Mr D, Mr E, and Mr G). Urinary, bowel and sexual function self-management was performed during the month following radiotherapy. However, this man reported little relief from his urinary and sexual function self-management behaviours over time.

Mr J (Metastatic Cancer, Hormone Therapy, Low Support)

Mr J was a 73-year-old married man with low social support. This man was diagnosed with metastatic prostate cancer and treated with hormone therapy. The social support constructs did not have any association with emotional outcome and therefore, the propositions of social support theory did not hold for Mr J. This finding featured in four previously reviewed case studies (Mr D, Mr E, Mr G, and Mr I). All four of these men had a different stage of cancer, treatment modality with a

spread of demographic characteristics and will be considered in the general discussion.

Mr J had the worse cancer staging compared to the previously reviewed studies but he did not report any self-management behaviours over time. This finding was counter-intuitive to the researcher's assumptions, because evidence has identified that men treated by hormone therapy often reported the worse HRQoL compared to other treatment modalities (Couper et al., 2009, Gacci et al., 2009, Sanda et al., 2008, Ash et al., 2007). Furthermore, men treated by hormone therapy can experience the following symptoms: nausea, decreased appetite, constipation and diarrhoea, gynecomastia, sleeping difficulties, sweats and flushes, depression and impotence (Cancer Research UK, 2011, Couper et al., 2009). Mr J frequently experienced impotence and urinary urgency during the day and night but did not report any self-management behaviours to relieve his symptoms. Due to the limitation of not having a measurement of symptom severity or symptom bother, it is possible that he did not perform self-management because 1) his symptoms were not severe, and 2) his symptoms did not bother him. Alternatively, Mr J was married with low social support and therefore, a further explanation could be that he did not have access to appropriate support (informational, practical, and emotional) to assist him in the self-management of his symptoms. This area would be worthy of additional research to provide useful insights to the influence of symptom bother on the frequency of self-management behaviours and the influence of low social support.

In summary, Mr J did not support the propositions of social support theory and this finding was similar to Mr D, Mr E, Mr G and Mr I. No self-management behaviours were reported, although Mr J frequently experienced urinary and sexual dysfunction.

Mr K (Metastatic Cancer, Hormone Therapy, High Support)

Mr K was a married 72-year-old man who had metastatic prostate cancer and was treated with hormone therapy. There were no associations between the social support constructs and negative affect and therefore, the propositions of social support theory did not hold within-person for Mr K. This is a finding that has

featured in five (Mr D, Mr E, Mr G, Mr I and Mr J) of the previously discussed cases and this will be further considered in the general discussion.

Mr K did not report any self-management behaviours and this finding was similar to Mr J who also had the same cancer stage and treatment modality. Mr K did experience a number of symptoms every day and these included: pain, tiredness, unable to sleep, urinary urgency and urinary frequency, but he did not perform any self-management behaviours. An interesting contrast between Mr K and Mr J is that the frequency of symptoms for Mr J was higher compared to Mr K. Mr J, who experienced a higher frequency of symptoms, had low social support, whereas Mr K, who experienced less frequent symptoms, had high social support. Whilst this is a tentative association that should be treated with caution, it is also related to a previously identified emergent theme. Men with low social support (Mr B, Mr G, and Mr I) displayed no trend of improved symptom relief from their self-management strategies. It is possible that social support may influence patient appraisal of stressful encounters (in this case frequency of symptoms) and minimise the effect of the stressor (symptoms). This was not tested using inferential statistics and therefore caution should be taken, but this is an emergent association that would be worthy of further research.

In summary, the propositions of the social support theories were not supported by Mr K's results. No self-management behaviours were reported, although a number of symptoms were experienced daily.

6.6.1 General discussion

The EMA adapted/N-of-1 design was acceptable for these men, which was demonstrated by the very high response rates. The eleven men were purposively sampled based on cancer stage (which enabled a broad range of treatment modalities to be studied) and different levels of social support. Four men (Mr A, Mr B, Mr C and Mr D) had localised cancer, five men (Mr E, Mr F, Mr G, Mr H and Mr I) had locally advanced cancer, and two men (Mr I and Mr J) had metastatic cancer. Together the eleven case studies have provided mixed findings for the propositions

of social support theories which (anecdotally) did not appear to be related to clinical characteristics or level of social support.

Two men (Mr A and Mr H) provided support for the propositions of the main effects social support model (Cohen et al., 2000, Cohen, 1988, Cohen and Hoberman, 1983) within-person design. For these men (Mr A and Mr H), perceived social support (perceived availability of social support at a time of need) was the most important social support construct that predicted emotional outcome. For these men, received social support did not significantly predict negative affect but perceived social support did. The findings from these two case studies suggest an exciting, but tentative, dimension to existing social support theory. Perceived social support was found to partially mediate the relationship between coping (positive and negative) and negative affect in both case studies (Mr A and Mr H). These finding have identified a causal link between coping and emotional outcome because of perceived social support for these men at that stage in their illness and in the situations reported. Clinically, this is an important finding (identified for Mr A and Mr H) because perceived social support bridged the relationship between negative coping and negative affect. The conditions for mediation were met based on the recommendations from Baron and Kenny (1986) for both men. The results of the Sobel's test and the bootstrapping procedure were significant for Mr A and non-significant for Mr H. In the aforementioned, this is a tentative conclusion because statistically significant results were only identified for Mr A (based on Sobel's test and bootstrapping results), but not for Mr H. This area would be worthy of further research to replicate perceived social support as a partial mediator between coping and negative affect.

The stress buffering model (moderation effects) (Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984) was supported by three men (Mr B, Mr C and Mr F). A similar moderation effect was found across the three case studies, but the three men differed in clinical characteristics and level of social support. Negative coping was associated with negative affect when received social support was low. These findings suggest that men do not always receive the appropriate support when they are experiencing negative coping and negative affect. This unique within-person assessment over time (Mr B, Mr C and Mr F) has demonstrated replication of this

moderating effect for three case studies. It has also identified a clinical area that would be worthy of further research. Additional work is needed to identify what types of support are most helpful to men and in what circumstances over the course of the prostate cancer journey. Surprisingly, negative effects of social support were also identified on emotional outcome.

For 2 men (Mr B and Mr F) received social support was predictive of higher negative affect and moderation effects were identified. For Mr B, received social support was a significant predictor of higher negative affect and, positive coping was associated with negative affect when received social support was high. These findings would be indicative that not all provisions of support are helpful. This is a paradoxical finding and does not support the main effects theoretical model or the stress buffering model. According to the social support theory (Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984), social support transactions are related to successful adaption and linked to improved health outcomes. These results may suggest that social support can be potentially harmful for some men. This result is in keeping with findings that have demonstrated the negative consequences of social support on health outcomes (Scholz et al., 2008, Schwarzer et al., 2006).

For six men (Mr D, Mr E, Mr G, Mr I and Mr J and Mr K) the propositions of social support theory were not supported at that stage in their illness and in the reported situations. The research design for the EMA adapted/N-of-1 has allowed replication, and this adds strength to this Ph.D. study. For these six men (Mr D, Mr E, Mr G, Mr I, Mr J and Mr K), they had a range of cancer stages, treatments and level of social support, among additional clinical and demographic variables. The sampling framework criteria enabled the propositions of social support theory to be tested with individuals with high support, and in individuals with low support. These six men (Mr D, Mr E, Mr G, Mr I, Mr J and Mr K) reported a range of high and low social support, but this did not influence the mechanism effect of social support on emotional outcome. No emergent commonality is evident to explain these non-statistically significant findings for social support theory for these six individuals.

Collectively, these findings suggest that social support intervention would not be appropriate for these (six) men, because the theorised process for social support

does not “work” for these individuals, and thus perhaps a social support intervention may not work. It is interesting that most theories, including social support theories, are within-person models, but most models are tested between people (such as the prospective surveys identified in chapter 2 and the results in chapter 5). In particular, the main effects model (Cohen et al., 2000, Cohen and Wills, 1985, Cohen and McKay, 1984) and the stress buffering model (Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984) have been supported in prostate cancer studies (Zhou et al., 2010a, Zhou et al., 2010b, Scholz et al., 2008, Visser et al., 2003), but when applied to the “individual man”, the theory does not hold within-person design for these six men at this stage in their cancer journey. This innovative Ph.D. study has demonstrated that the propositions of social support theory are supported between people (chapter 2 and chapter 5), but it does not hold within-person design for these six men (Mr D, Mr E, Mr G, Mr I and Mr J and Mr K).

There are a number of possible explanations to account for this finding. Interestingly, the majority of men (80%) in this Ph.D. study did not use additional cancer support services, such as: Support Groups or Maggie’s Cancer Care Centre. These data are consistent with those published by Shapiro et al., (2004) and Krizek et al., (1999), who reported that only 22% of men expressed an interest in cancer support services. Therefore, clinically, does current healthcare effectively meet the supportive care needs for men affected by prostate cancer? It is apparent that for the majority of men who are affected by prostate cancer, they are unlikely to participate in the supportive services available to them. This case series (six) identified no relationship between coping and social support, or on emotional well-being; and for two men (Mr B and Mr F), negative effects of social support were identified. Clinically, this phenomenon requires additional research because the benefits of social support for men affected by prostate cancer are unclear based on the results of the case series.

Descriptively, men treated with invasive treatment (surgery and radiotherapy) (Mr C, Mr D, Mr E, Mr F, Mr G, Mr H) performed self-management behaviours more frequently over time compared to men (Mr A, Mr B and Mr J and Mr K) treated conservatively. Men performed self-management behaviours to reduce the effects of their prostate cancer and side effects from their treatment. Three men (Mr B, Mr

G, and Mr I) reported little relief from their self-management behaviours and all three men reported low social support. For these men they may not have had access to the appropriate social support to help them to self-manage their symptoms, for example, informational or practical support. Alternatively, social support was not salient in particular situations. A further interesting finding was that men (Mr J and Mr K) with the most severe stage of cancer (metastatic cancer) who were treated by hormone therapy did not report any self-management behaviours. As identified in chapter 1, men treated with hormone therapy can often experience the worse HRQoL (Couper et al., 2009, Gacci et al., 2009, Sanda et al., 2008, Ash et al., 2007, DePuy et al., 2007, Kato et al., 2007). Both men experienced a number of frequent symptoms every day and these included: pain, tiredness, unable to sleep, urinary urgency and urinary frequency. It is possible that for these men (Mr J and Mr K), they were not bothered by their symptoms, and therefore, they did not feel it necessary to perform self-management. One explanation could be related to symptom severity, symptom bother, and the relevance of time in relation to treatment, among many other factors, that influenced mens' self-management behaviours, or, lack of.

The symptom experience includes an individual's perception of a symptom, evaluation of the meaning of a symptom, and response to a symptom (Dodd et al., 2001). Perception of a symptom signifies whether an individual notices a change from the way they usually feel, or behave. Individuals evaluate their symptoms by making judgements about the severity, cause, treatability, and effect of the symptoms on their daily lives. Responses to symptoms can include the following: psychological, physiological, sociocultural and behavioural components (Dodd et al., 2001; Lenz et al., 1997). Thus, for men with prostate cancer symptom experience is complex, and conceptualised as a multidimensional experience, with a number of factors that may influence a man's decision to perform self-management of their symptoms. Such factors might include: symptoms intensity (strength or severity), timing (duration and frequency of occurrence), level of perceived distress (degree of discomfort or bother) (Lenz et al., 1997), and perceived self-efficacy (Bandura, 1997).

Symptom intensity refers to the severity, or strength, of a symptoms being experienced. Whereas, the time dimension includes the frequency in which a symptom occurs, the duration of a symptom, or can represent the timing of a

symptom occurrence relative to specific activities (for example, the temporal association of nausea and food intake). The distress dimension of symptom experience refers to the degree to which a person is bothered by their symptoms. Patients are often asked to indicate how much they are bothered by a symptom to gain an understanding of how they are interpreting the experience, and the meaning they are assigning to the symptom experience.

Further research is needed to understand the relationship between symptom experience and self-management for men living with and beyond prostate cancer. For example, at what stage in a man's recovery from treatment does self-management of sexual dysfunction become salient? Some qualitative research would be advantageous in this area to explore factors that influence a man's decision to perform self-management over time.

Strengths and limitations of the EMA adapted/N-of-1

There are a number of strengths to the EMA adapted/N-of-1 design. This is the first study that has explored the feasibility of real time data collection methods within "individual men" affected by prostate cancer over time. This study assessed self-management behaviours and tested social support theory (Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984) in eleven men with different clinical characteristics and demographic backgrounds, enabling some replication. This study has provided a unique insight into the individual experiences of men that minimised retrospective memory recall and reduced data fabrication. This is one of the first studies to examine real time self-management behaviours for men affected by prostate cancer with a range of treatment modalities and stage of cancer. However, there are a few limitations to what can be concluded from this case series (11). This study assessed men's experiences three times per day for one month and therefore, assessment of self-management behaviours and social supportive experiences beyond the period assessed in this Ph.D. study is unknown. Given the distinct benefits of real time data, additional research using innovative technology is needed to identify the survivorship needs of men at different stages of the cancer journey.

The regression analyses were sufficiently powered in the seven case studies (Mr A, Mr B, Mr C, Mr F, Mr G, Mr H and Mr I) based on recommendations from Tabachnick

and Fidell (2007). However, each regression model explained approximately 30% of the variance of the dependent variable (negative affect) which left a proportion of the variance unexplained by the model. The amount of variance explained by testing the propositions of social support theory was similar between the prospective longitudinal study (chapter 5) and these case studies. Additional variables may have had a significant multivariate contribution, but this would have under-powered the regression analyses in the case studies. The measures used in the study appeared valid and reliable, but because the case studies reported here used measurements relatively untested in single-case designs, the reliability is unclear. The measures used in the EMA adapted/N-of-1 were developed based upon existing standardised instruments, and face validity was checked by feedback from patients and clinicians and from the results of the pilot. Establishing the reliability of the diary questionnaire is somewhat problematic because of autocorrelation and pre-whitening procedures. The influences of autocorrelation and pre-whitening of variables on Cronbach's alpha statistic are unknown and therefore, Cronbach's alpha testing was not performed in the eleven case studies. Some caution should be taken in the interpretation of these findings as this may have introduced measurement error. Testing the propositions of social support theory and assessing self-management behaviours within individuals affected by prostate cancer using a repeated measurement design, is uncharted territory for nursing research. Future research using repeated measures in within-person designs is needed to support or refute these findings because of the uncertainty of comparing group-based findings to single-case data. Therefore, the conclusions from these eleven case studies should be considered provisional.

A number of symptoms were not explicitly assessed, and included the following: pain/proctitis, leakage of stools, hot flushes, painful nipples or breasts, blood in stools, oedema, bloated abdomen, weight loss, weight gain; but the participants were given an opportunity to share these symptoms by "free text" in the diary entry. It is important to acknowledge that the participants may not have used the "free text" option to report additional symptoms; therefore, the symptoms experienced could be unrelated to the self-management behaviours reported. For example, constipation and diarrhoea was explicitly assessed, but not blood in stools, or proctitis, and therefore; the reported behaviours could be related to other symptoms for which no data was captured.

There is an important distinction between statistical significance and clinical significance, and this is an area which has been contested by researchers over the years. Statistical significance refers to real differences, as opposed to ones that are illusory, questionable or unreliable. A statistically significant result indicates that we can be confident that study findings are not by chance (Ogles et al., 2001). For example, statistical tests comparing the mean and variance differences which are found beyond the range of chance (usually at the .05 alpha levels) are usually deemed as "statistically significant". One of the problems for clinicians who attempt to make practical applications of the statistically significant results is the lack of information regarding the clinical significance of research findings, and this is a particular limitation of the EMA adapted/N-of-1 case series. Clinical significance refers to changes that are practically meaningful for a patient and clinician (Jacobson and Truax, 1991; Jacobson et al., 1999; Kendall, 1999; McGlinchey et al., 2002; Turner and Turk, 2008). Little guidance exists to establish the clinical significance for EMA adapted/N-of-1 research designs. There are a number of potential clinically relevant findings and these included: perceived social support bridged the relationship between coping and negative affect, negative effects of social support were found, an arbitrary association was found for invasive treatments and increased number of self-management behaviours performed, and finally, men reported little relief from self-management behaviours. Ultimately, the clinical significance of these findings will remain unknown. However, one approach that may have provided an account of the clinical significance of these findings would have been to explore these findings with the patient using qualitative interviews.

6.7 Conclusion

Collectively, the findings from the eleven case studies have provided mixed support for the propositions for social support theory and it appears that one size does not fit all. Three men provided support for the main effects and stress buffering model, two men identified negative effects of social support, and men (six men) did not support existing social support theory. The propositions of social support theory are supported between people (chapter 2 and chapter 5), but failed to work within these six men, and negative effects of social support were also identified for two men. These results suggest that the development of a social support intervention would

potentially benefit 3 individuals from this case (11) series. The negative effects of social support for two men cannot be ignored, and completely contradicts social support propositions. Therefore, future research would be important for testing and developing social support theory at the within-person level.

Variance was identified when examining the social support constructs (perceived, received and satisfaction with social support) over time. These findings demonstrate that traditional standardised instruments cannot accurately detail the intra-individual social supportive experiences over time. Importantly, all of the men, with the exception of Mr A, Mr C and Mr F, reported reduced satisfaction levels with their support over time and thus additional work are needed in this area.

The number of days that men performed self-management to relieve urinary, bowel and sexual dysfunction varied across the eleven single-case studies. Men treated with invasive treatment (surgery and radiotherapy) (Mr C, Mr D, Mr E, Mr F, Mr G, Mr H) performed self-management behaviours more frequently over time compared to men (Mr A, Mr B and Mr J and Mr K) treated conservatively. Each individual man performed self-management behaviours to reduce the effects of their prostate cancer and side effects from their treatment.

Men diagnosed with localised and locally advanced cancer performed self-management, but men diagnosed with metastatic cancer did not perform self-management. Additional future research would be helpful to understand why men with metastatic cancer did not report any self-management. A common theme across the eleven case studies was that men frequently experienced a range of symptoms, including: tiredness, urinary symptoms, bowel symptoms and impotence, but no self-management behaviours were reported. Future research is needed to understanding the relationship between symptom severity, bother, and frequency with self-management behaviours, and is a prerequisite to further advance knowledge and understanding in the area of self-management support. An understanding in this area is urgently needed and has been informed from the results of these eleven case studies and from the findings from chapter 5. Knowledge in this area may enable tailored evidence-based self-management advice to be provided and tailored to the individual needs for men affected by prostate cancer survivors.

7.0 Summary, clinical implications, and future research

This innovative Ph.D. study has added to the HRQoL, social support, and self-management literatures reviewed in chapters 1, 2, and 3. The knowledge contribution from this study will be identified and discussed in relation to HRQoL, social support and self-management. There are a number of strengths to this Ph.D. study that have complemented the existing methodological and clinical implications in this field. However, there are a number of limitations that featured in this Ph.D. study and these shall be acknowledged and detailed. This chapter concludes with the next steps for taking forward this important research and details future plans for Post-Doctoral research and activity.

7.1 Health-related quality of life

The HRQoL findings from the prospective longitudinal study (chapter 5) are in keeping with the literatures analysed in chapter 1, and build upon the literatures reviewed in chapter 2. Global quality of life (EORTC C30) was positively associated with the EORTC C30 functional scales and negatively correlated with the individual symptom scales. The finding from the hierarchical multiple regression analyses demonstrated longitudinal predictors of global quality of life at six months with the following baseline variables: global quality of life, perceived social support and satisfaction with social support, and adds to the HRQoL evidence-base. This Ph.D. study used a multidimensional approach to social support measurement and has added clarification to the existing knowledge-base. Perceived social support and satisfaction with social support were longitudinal predictors of HRQoL at 6 months, but received social support at baseline was not. The correlation coefficients identified baseline positive coping had no association with global quality of life at six months, and baseline negative coping was entered into the regression equation at <.15, but did not significantly predict global quality of life for prostate cancer survivors. The clinical implications of the regression analyses, suggest that perceived social support and satisfaction with social support at diagnosis could be a potential intervention target to improve HRQoL at 6 months after diagnosis. Perceived social support has been found to reflect more of a personality disposition (Sarason et al.,

1986) that is intertwined with optimism, rather than actual social support transactions. Thus, intervention design could be problematic for this construct because altering personality-level variables are difficult to design. One approach to improving men's perceived social support could be cognitive behavioural therapy (Sheldon, 2011). Cognitive behavioural therapy is an evidence-based psychological approach that is practiced by a range of healthcare professionals and therefore, could have the potential to improve men's perceptions of social support.

Ideally, future research should be designed to evaluate the extent to which HRQoL can be influenced by the typologies of social support (informational, emotional, financial, and instrumental) which are provided by different sources (for example, family members, clinicians, specialist nurses, and friends) and at different time points in the cancer journey. There needs to be a complementary transition in social support cancer research, from using standardised measures (aggregate group level approaches), towards the study of more explicit, specific behaviours that occur between a man with prostate cancer, and those individuals in his support network. Future work is needed to advance our understanding into the perspective of the provider, as well as the recipient, in obtaining judgements about the effectiveness of the typologies of social support, social support interactions, over the cancer continuum in relation to HRQoL.

There were a number of statistically significant and clinically relevant changes in HRQoL over time. Global quality of life scores reduced over time and were found to have a small clinically relevant change (Osoba, 2011, Osoba, 2000). For the most part, functional domains of HRQoL were mostly unaffected (role function, cognitive function, emotional function, and social function) except for reduced physical function scores at six months. Overall, the EORTC functional scores were similar to normative EORTC C30 data (Scott et al., 2008) and are in keeping with studies reviewed in chapter 1 (Hashine et al., 2009, Kato et al., 2007, Namiki et al., 2006b, Robinson et al., 1999a). A number of statistically significant increases were found for the following symptoms: fatigue, constipation and appetite loss, but not for dyspnoea, pain, diarrhoea, and financial difficulties. Appetite loss, constipation and fatigue were significantly worse at six months, but not clinically significant (Osoba,

2011, Osoba, 2000) and this is similar to other published work (Lips et al., 2009, Spry et al., 2006, Robinson et al., 1999a).

Statistically significant increases were identified for bowel symptoms and treatment symptoms at six months, and represented small clinical changes; but urinary symptoms did not significantly change over time. Sexual activity statistically reduced over time and represented a small clinically significant change. At one month after diagnosis, twenty-eight (41.2%) men were sexually active, and at six months fifteen men (22.1%) were sexually active. Reduced sexual activity for men living with prostate cancer has been widely demonstrated in published studies which assessed change over time (Roeloffzen et al., 2010, Smith et al., 2009, Nguyen et al., 2009, Davison et al., 2007, Kato et al., 2007, Namiki et al., 2007, Jayadevappa et al., 2006, Feigenberg et al., 2005). Overall, the results for HRQoL in the current study appear to be consistent with other published data. Due to the limited follow-up period, it was not possible to evaluate changes in HRQoL beyond six months.

7.2 Social support

The findings from chapter 5 and 6 explored the underlying mechanism effect between coping and social support on HRQoL between individuals and within individuals over time. These findings have built upon the literatures analysed in chapter 2, and inform a number of important implications for social support theory. This Ph.D. study was theoretically driven and has enhanced and refined our understanding of the social support constructs, and the propositions of social support theory (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984, Cohen and Hoberman, 1983) for men affected by prostate cancer. Chapter 5 presented the findings from the prospective longitudinal study (aggregate group level effects) which used a multidimensional assessment of the social support constructs. The findings from chapter 5 identified perceived social support and satisfaction with social support (baseline, before treatment) predicted better global quality of life at six months, but only perceived social support (at baseline) predicted less depression at six months. Received social support did not have any significant relationship with the dependent variables (anxiety, depression and global quality of life). In addition, the social support constructs (perceived, received and satisfaction with social support) did not have a significant relationship with anxiety at six months. Collectively, the findings from the multiple regression analyses would indicate that

perceived social support at baseline was the most important social support construct that predicted better global quality of life and less depression at six months, and this is in keeping with existing literatures (Zhou et al., 2010a, Mehnert et al., 2010, Andel et al., 2004, Visser et al., 2003, Rondorf-Klym and Colling, 2003).

Existing studies (Zhou et al., 2010a, Mehnert et al., 2010, Andel et al., 2004, Visser et al., 2003, Rondorf-Klym and Colling, 2003) did not use a multidimensional assessment of social support, but rather, the social support assessment was restricted to perceived social support only. Therefore, this Ph.D. study adds an important dimension because of the three social support constructs assessed (perceived social support, received social support and satisfaction with social support); perceived social support and satisfaction with social support were found to predict better health outcomes for men at 6 months.

Based on the findings from the prospective longitudinal survey, no moderation or mediating effects were identified between coping and social support on global quality of life, anxiety, and depression. The buffering model (Cohen et al., 2000, Cohen, 1988, Cohen and Wills, 1985, Cohen and McKay, 1984, Cohen and Hoberman, 1983) was not supported. Based on these results alone it could be assumed that perceived social support could be considered as a potential psycho-social factor that may improve HRQoL and this has been supported elsewhere (Zhou et al., 2010a, Zhou et al., 2010b). However, the findings from the series of eleven case studies challenge the suitability of such an intervention for “all men” affected by prostate cancer.

The series of EMA adapted/N-of-1 case studies evaluated change over time and tested existing theoretical social support models within eleven individuals over time. Collectively, different results were obtained across the eleven men that linked coping and social support to emotional outcome. The findings for two men (Mr A and Mr H) provided support for the propositions of the main effects model (Cohen et al., 2000, Cohen, 1988). Perceived social support (perceived social support at a time of need) was the most important social support construct that predicted emotional outcome. The findings for these case studies (Mr A and Mr H) suggest an exciting, but tentative, dimension to social support theory. Perceived social support was found to partially

mediate the relationship between negative coping and emotional outcome for Mr A and Mr H. An intervention targeting perceived social support to improve HRQoL as identified from the prospective longitudinal study (chapter 5) and recommended by (Zhou et al., 2010a, Zhou et al., 2010b) may have been suitable for both of these men. Yet, for others, it would appear that targeting perceived social support for an intervention study would not be appropriate. For other men, received social support was more important.

The findings from three case studies (Mr B, Mr C and Mr F) identified a similar moderation effect and support the buffering model within-person design (Cohen et al., 2000, Cohen, 1988, Cohen and McKay, 1984). Negative coping was associated with emotional outcome when received social support was low for these three men. These findings suggest that men do not always receive appropriate social support when they are experiencing negative coping and negative affect. Clinically, this is an important area for future research. Additional research is needed to identify what types of social support (informational, emotional, practical and financial) are most helpful to men, and from which support provider, and in what circumstances over the course of living with and beyond prostate cancer. There is a notion that social support has a positive effect on influencing physical and psychological well-being, but quite the reverse was identified for two men. Negative effects of social support were identified for Mr B and Mr F.

Received social support was predictive of higher negative affect, and positive coping was associated with negative affect when received social support was high. Importantly, these findings are indicative that not all provisions of social support are helpful for prostate cancer survivors. These findings (Mr B and Mr F) would suggest that their social support was mismatched to their needs. A further explanation is that some individuals produce better coping efforts when one masters challenges alone, without help from others, and will only resort to the receipt of social support in the worst circumstances. Alternatively, a man with prostate cancer can experience stress and difficulties with their interpersonal relationships. A man's uncertainties and fears can increase their need for support; while the intense fears and the stigma associated with the disease, may create communication problems that decrease their access to social support. For example, a man with prostate cancer who faces sexual

problems can elicit negative feelings and frustrations in others because of his own expression of frustrations and fears in coping with erectile dysfunction. This can lead others to behave towards a man with prostate cancer in ways that are unsupportive because of communication barriers. The support needs of men with prostate cancer may vary with the adaptive challenges they confront, for example, coping with diagnosis, the physical and psychological problems after treatment; thus it is important that men have access to multiple types of social support (information, emotional and instrumental) as they need it. This reinforces the need for further research to identify what types of social support are most helpful to men, and in what circumstances over the cancer journey.

For six men, the propositions of social support theory were not supported at all. The findings from the series of case studies would suggest that developing an intervention study based on the propositions of social support theory would not be appropriate for all men. This is perhaps in keeping with the results in chapter 2 and chapter 5, because only a small minority (20% of the study population) participated in cancer support services and this has been reported elsewhere (Shapiro et al., 2004, Krizek et al., 1999). In addition, previously published social support intervention studies (Zhang et al., 2007, Northouse et al., 2007b, Carmack Taylor et al., 2006) did not have a significant effect on improved HRQoL for men affected by prostate cancer. The findings from this case series (Molenaar, 2004) have informed the theoretical modelling stage of the Medical Research Council's framework for complex interventions (Craig et al., 2008). These findings suggest that underpinning a future intervention study by the propositions of social support theory would not be suitable for all men, because these findings have demonstrated that one size does not fit all.

7.3 Self-management

The findings from the prospective longitudinal study (chapter 5) have built upon the literatures analysed in chapter 3. This study has identified that men performed a number of self-management behaviours for urinary, bowel, and sexual dysfunction across all stages of disease; and this adds to the existing evidence-base. At six months, urinary self-management significantly reduced, bowel self-management significantly increased, and sexual function self-management increased over time;

but failed to reach statistical significance. The clinical relevance of these findings is in keeping with the clinical characteristics of the study sample, because most men were treated with radiotherapy, and bowel problems are prevalent in men treated by this modality. A commonality across all stages of the disease was that men reported little relief from their self-management behaviours over time. There are a number of explanations to explain why men may have reported little relief from their self-management. One possible explanation relates to the sources of self-management advice. The most frequent source of self-management advice came from men's partners'. It can be argued that partners (to the exception of partners with expert healthcare knowledge) do not have an appropriate level for knowledge; for example, educating men on the usage of penile inserts, or penis pumps for the self-management of erectile dysfunction; but partners could be ideally suited to offer emotional support, for example. Further work is needed to establish why men frequently sourced self-management suggestions from their partners, and not from healthcare professionals, as an important step towards developing our understanding of the implications of partners providing self-management advice from the man's perspective, but also from the partner's perspective.

A further important contribution to the evidence-base is surrounding self-efficacy. Self-efficacy scores at six months were found to be statistically worse when compared to baseline (chapter 5). These data suggest that men living with and beyond cancer may experience a decline in their belief to perform self-management with confidence and ease over time. This is a key clinical finding that would be worthy of future research to advance our understanding as to why men may experience a reduction in self-management self-efficacy over time. In the aforementioned, men reported little relief from their self-management behaviours over time, and this could be related to men's reduced self-efficacy scores at six months. According to Bandura's theory of self-efficacy, self-efficacy is the belief that a person can master a situation, and produce a positive outcome. In keeping with Bandura's theory, men consistently reported little relief from their self-management behaviours for urinary, bowel and sexual dysfunction, which may have reduce mens' confidence and ease to perform their self-management over time. Improving men's self-efficacy would be an important intervention target, but additional research is prior needed to ensure intervention work is appropriately informed.

The findings from the EMA adapted/N-of-1 case series complemented and extended the contribution of the prospective longitudinal self-management findings. Descriptively, men treated with invasive treatment (surgery and radiotherapy) (Mr C, Mr D, Mr E, Mr F, Mr G and Mr H) performed self-management behaviours more frequently over time compared to men (Mr A, Mr B, Mr J and Mr K) treated conservatively. The self-management behaviours were mainly related to three areas: urinary, bowel and sexual dysfunction, but men also experienced other problems for which they performed self-management and these included: radiation burns, infected surgical wound, ankle oedema, stress and relaxation problems. Variation was identified across the eleven case studies for the following: symptoms, self-management behaviours and self-management relief. A clinically important theme was identified from the case series in that men frequently experienced a range of symptoms but did not perform any self-management. The reasons as to why men did not perform self-management for these symptoms are unclear and several explanations have been discussed in this thesis. Key to advancing the field of self-management for men living with and beyond cancer is knowledge into men's symptom experience. Symptom experience is complex with a number of factors that may influence a man's decision to perform self-management of their symptoms. Area's for future research should focus on developing our understanding of the following: symptoms intensity (strength or severity), timing (duration and frequency of occurrence), level of perceived distress (degree of discomfort or bother) (Lenz et al., 1997), and perceived self-efficacy (Bandura, 1997), as potential antecedents for self-management behaviour. A suitable theoretical framework that could be used in for future research is the Theory of Symptom Self-Management (Hoffman, 2013) because it identifies multiple components such as: patient characteristics, symptom assessment, perceived self-efficacy for symptom management, symptom self-management behaviours, and performance outcomes. Developing our knowledge and understanding in this area may shed a very helpful clinical insight into the changes in symptoms experienced and their relationship to self-management behaviour, and subsequent HRQoL. Currently, this area is massively under-researched and is considered as a very important target for future work.

7.4 Study limitations

There were a number of methodological limitations that featured in the prospective longitudinal study and the EMA adapted/N-of-1 series. The regression analyses performed were very marginally underpowered in both the longitudinal study and the EMA adapted/N-of-1 series and therefore, it was not appropriate to add additional predictors as this would have caused the analyses to be significantly underpowered. It is very likely that other variables would have had a significant multivariate contribution to the regression models, but were not included. In addition, a large number of statistical tests were performed that may have resulted in a type 1 statistical error. To overcome this limitation in future studies it would be advisable to use a bonferroni adjustment (setting a more stringent alpha level for each comparison). As a result, some caution should be taken in the interpretation of these findings, and requires the study to be replicated with large sample sizes. One suggestion would be to consider a multi-centre study to increase the sample size and generalisabilty of future findings.

The measures used in the longitudinal study were reliable and valid, but retrospective memory recall bias was likely. In addition, this study only followed men up to six months; therefore changes beyond 6 months are unknown for this study sample. The measures used in the electronic behavioural diary appeared valid and reliable. Face validity of the content of the diary schedule was verified through expert comment from urological clinicians and prostate cancer patients. However, reliability of the diary schedule was not demonstrated and therefore, a degree of caution should be taken in the interpretation of the findings. There is a growing interest in real time data collection technologies in healthcare research, but very little guidance exists how to establish reliability in N-of-1 diary studies, due to the influence of autocorrelation and pre-whitening. Future research studies using N-of-1 diary methods should give due caution and explore statistical approaches to establish reliability. One approach that might be considered in the future, with the benefit of hindsight, would be to develop the diary measures in conjunction with each study participant. This strategy could be used to help reflect and capture the individual patient's meaning of a particular construct. In addition, the EMA adapted/N-of-1 method is a new innovative approach that has never been applied to prostate cancer

survivors before. Therefore, this made the interpretation of the findings challenging because no existing data was available to compare the EMA adapted/N-of-1 findings to. In terms of lessons learned, it would have been extremely valuable to have conducted a semi-structured interview with each participant following the analysis of their diary data, with the purpose to confirm, refute, and explore the findings with each individual study participant. A further limitation to the EMA adapted/N-of-1 design was that the questionnaire schedule asked about men's experiences over the past few hours; and thus may have introduced a small amount of memory recall.

It is important to acknowledge the potential limitation of the search strategy used in the self-management review (chapter 3). The search terms used had a high level of specificity, and therefore, the search terms may not have been sensitive in identifying all relevant literatures for the self-management review. An important omission in this review was that "coping and adjustment" were not included in the search terms, and as a result, it is possible that not all relevant literatures were reviewed. Furthermore, a potential limitation of the review method used was that inclusion criteria consisted of the levels of evidence, and therefore, potentially relevant studies may have been excluded because of research design.

An important consideration for bias exists in the diary assessment of symptoms. The symptoms chosen were informed by the EORTC C30 and PR25, discussions with clinicians, and men with prostate cancer. A number of symptoms were not explicitly assessed, and included the following: pain/proctitis, leakage of stools, hot flushes, painful nipples or breasts, blood in stools, oedema, bloated abdomen, weight loss, weight gain; however, the participants were given an opportunity to share these symptoms by "free text" in the diary entry. It is important to acknowledge that the participants may not have used the "free text" option to report additional symptoms. As a result, the symptoms conveyed could have been unrelated to the self-management behaviours reported. For example, constipation and diarrhoea was explicitly assessed, but not blood in stools, or proctitis, and therefore; the reported behaviours could be related to other symptoms for which no data was captured.

The standardised measures used in the prospective longitudinal study had demonstrated reliability and validity and have been used in many prostate cancer

studies, which added strength to the study, and enabled comparison of the study findings. However, it is possible that some of the standardised measures may have been measuring the same construct, that is to say, the HADS, MAC Scale, EORTC C30 and PSS. For example, negative coping on the MAC Scale was significantly correlated ($r=.512$, $p<.01$) with anxiety on the HADS scale. A potential exists that the relationships between the constructs measured could have been an artefact of standardised instruments measuring the same thing. Therefore, a degree of caution should be taken in the interpretation of the findings.

7.5 Methodological and clinical implications

The findings from this Ph.D. study have identified men may benefit from an intervention study to improve HRQoL, self-management self-efficacy and symptom management. However, the content and theoretical model to develop such an intervention study would have to be considered. The findings from the case series identified that "one size does not fit all" and therefore, future interventions should be tailored to the "individual man's needs". This, however, is a very challenging and ambitious prospect for the most talented of researchers. A prerequisite to nursing care is to ensure that the care delivered is holistic and personalised to the individual needs of each patient, and future research should be developed on this premise.

The findings from the longitudinal survey (chapter 5) and EMA adapted/N-of-1 series (chapter 6) identified a number of important clinical implications. No statistically significant changes were identified over time in anxiety and depression scores. However, using the cut-off scores as recommended by (Snaith and Zigmond, 1986) a trend (arbitrary) for increased anxiety and depression was identified for some individuals at six months. Healthcare professionals should have awareness that emotional distress is likely for some men who are affected by prostate cancer and they should screen for, and treat, as appropriate. Global quality of life demonstrated a clinically small and statistically significant decrease at six months, but the functional domains of the EORTC C30 were mostly unaffected, and this is very similar to other research in this field. Disease-specific domains were affected and an increase in bowel and sexual dysfunction was identified at six months. This is in keeping with literatures analysed in chapter 1. The findings from the EMA adapted N-of-1 series

identified that men can also experience a number of additional problems, such as: urinary symptoms, radiation burns, post-operative wound infection, ankle oedema, stress and relaxation problems for which men performed self-management. Overall, men reported little relief from their self-management behaviours and these results would, therefore, indicate that men may benefit from self-management support from healthcare professionals.

Men frequently relied on self-management suggestions from their partners at both, pre-treatment and at six months follow-up; and specialist nurses were infrequently reported as a source for self-management suggestions. Arguably, specialist nurses are ideally suited to provide expert evidence-based self-management advice and support (Ream et al., 2009, Faithfull et al., 2001), and therefore, clinically the current service provision and access to specialist nurses perhaps should be reviewed. Elsewhere, it is acknowledged that not all men with prostate cancer have access to a prostate cancer specialist nurse (National Audit Office and Department of Health 2005), and equity of access is increasingly more difficult to achieve due to the financial constraints within the NHS. Whilst access to specialist nurses may have been problematic, men do not always verbalise their concerns aloud to healthcare professionals because of embarrassment, and feeling of shame in their altered physical condition (George and Fleming, 2009, Braider, 2010). Importantly, this Ph.D. study has added an important contribution to this field, because the feasibility of real time patient reported outcomes in the home environment has been demonstrated. This innovative approach enabled the men to share their symptoms, supportive experiences, coping efforts, and self-management behaviours; without having to verbalise their concerns aloud. The use of mobile information and communication technology may be seen as a means to identify, and manage, the support needs of prostate cancer survivors in the future but additional field work is needed.

A further clinical consideration was that men reported a lack of satisfaction with their social support over time. Men should receive the right types of social support (information, emotional, instrumental, and financial) to match their individual needs over the cancer journey. The findings would suggest that further research is urgently needed to identify what are the optimum types of social support, and in what circumstances for men living with and beyond prostate cancer. The findings also

identified negative effects of social support and thus, not all types of social support are helpful for men with prostate cancer. One approach in the short-term could be to utilise the Bottomley Cancer Support Scale as a screening tool in clinical practice to identify men who may be at risk of inadequate social support provision. This questionnaire has only 9 items and therefore, would not be overly time-consuming in clinical practice.

A further clinical consideration was that only a small minority (approximately 20%) of men used additional cancer support services such as Maggie's Cancer Care Centre or Prostate Cancer Support Groups. This is not a new emergent finding and is in keeping with existing literatures, but this is a really important and, clinically, very relevant area to understand; how are the other 80% of men living with and beyond prostate cancer being supported? Perhaps this outcome challenges the suitability of additional cancer support services for the majority of men affected by prostate cancer. This area would be worthy of additional research to identify men's preferences for additional cancer support services.

This Ph.D. study has identified a number of areas for future research and perhaps supports the development of an intervention study aimed at improving health-related quality of life, self-care self-efficacy and men's symptom self-management. However, the content of such an intervention would have to be further considered, as would the theoretical model. Collectively, the findings from the eleven case studies have provided mixed support for the propositions of social support theory and it appears that one size does not fit all. Therefore, any future intervention study should be tailored to meet "individual man's needs".

This unique Ph.D. study has demonstrated the limitations of aggregate group level effects because such approaches inhibit our understanding of the individual person experience over time. Real time data collection moves far beyond traditional retrospective evaluations, enabling a much clearer understanding of person experience over time whilst minimising retrospective memory recall bias. This Ph.D. study has demonstrated the feasibility and acceptability of e-health technologies in men affected by prostate cancer, and therefore, using such methodological approaches in the future would be considered appropriate and beneficial.

7.6 Future plans

This study has contributed towards the first stage of the MRC's framework for complex interventions. However, additional future research is required to inform the content of such an intervention study. This Ph.D. study has identified areas for potential intervention and these include: self-management self-efficacy, HRQoL, and symptom self-management. Symptom experience for a man living with and beyond prostate cancer is complex, and there are a number of potential antecedents that may influence a man's decision, and ability, to perform self-management. Post-doctoral research will focus on developing and expanding the evidence-base to explore and identify antecedents of self-management for men living with and beyond prostate cancer. Areas for future research will focus on developing the knowledge-base for a range of clinical (for example: stage, treatment, existing co-morbidity) and demographic (for example: age, marital status, education, employment, socio-economic status) characteristics across the following areas of symptom experience: symptom intensity (strength or severity), timing (duration and frequency of occurrence), level of perceived distress (degree of discomfort or bother) (Lenz et al., 1997), and perceived self-efficacy, as potential predictors of self-management. A potential theoretical model might include the Theory of Symptom Self-Management (Hoffman, 2013) because it includes multiple components that would be helpful for nurses and clinicians to identify the numerous factors that may contribute to a man's experience of self-management.

Developing the knowledge-base that identifies which antecedents can influence a man's decision, and ability to self-manage, is a prerequisite to informing the content of a self-management support intervention study. Further work is also needed to establish why men frequently sourced self-management suggestions from their partners, and not from healthcare professionals, to understand the implications of partners providing self-management advice from the man's perspective, but also from the partner's perspective.

The Ph.D. study has illuminated the need for a complementary shift in social support cancer research, from using multidimensional standardised measures which are analysed using aggregate group level statistics; towards the study of more explicit,

specific behaviours that occur between a man with prostate cancer, and those individuals in his support network (including family, friends, healthcare professionals, etc.). Future work will also focus on advancing an understanding into the perspective of the support provider, as well as the recipient, in obtaining judgements about the effectiveness of the typologies of social support, and social support interactions over the cancer journey.

This exploratory Ph.D. study has provided a foundation to inform future research directions in this important field. In conjunction with taking forward the future research endeavours, a publication plan has been developed to disseminate the original contribution of this Ph.D. in peer-reviewed journals.

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Appendix 1.1 Inclusion/Exclusion Pro forma Checklist

Abstract Inclusion/Exclusion Checklist

Database_____

Abstract number_____

Authors and Year_____

Inclusion

	TICK
1. Levels of evidence A1-B3 (RCTs and systematic reviews, Individual well-designed non-experimental studies, controlling statistically if appropriate. Includes case control, longitudinal, cohort, matched pairs or cross-sectional random sample methodologies, and well-designed qualitative studies, well-designed analytical studies including secondary analysis)	
2. Does this title/abstract identify predictor variables of HRQoL and how HRQoL changes overtime?	
3. Identifies change overtime only.	
4. Published between 2005 and 2010?	

Exclusion

	TICK
1. Levels of evidence D-C1 (descriptive and other research or evaluations not in B (e.g. convenience samples, case studies and examples of good practice, summary review articles and discussions of relevant literature and conference proceedings not otherwise classified). Cross-sectional convenience samples.	
2. Pharmacological intervention studies/with the exception of hormonal treatment.	
3. Has other cancer sites included in paper i.e. Breast cancer	
3. Does not identify either predictor variables of HRQoL, or how HRQoL changes over time.	
4. Published before 2005?	

Instruction: Retrieval of full-text article

YES (Tick)	No (Tick)	Not Sure (Tick)

Appendix 1.2 Quality Assessment Tools

Quality assessment for qualitative studies (Shaw et al., 2009)

	Criteria	Yes (2/good)	Partial (1/fair)	No (0/poor)	score
	Study aims & context				
1.	Is the research question sufficiently described?	Research question clearly identified by the end of the research process, if not at the outset.	Research question or objective is vaguely/incompletely reported.	Question or objective is not reported, *or* is incomprehensible.	
2.	Is qualitative method appropriate?	Qualitative method is appropriate for the aims and the qualitative framework is identified and justified.	Qualitative method appropriate but the methodological framework unclear or not adequately justified.	Qualitative methods inappropriate for the aims.	
3.	Is the setting/context clearly described?	Context/setting is clearly described, permitting the reader to relate the findings to other settings.	The context/setting is partially described.	The context/setting is not described.	
	Sampling				
4.	Is the sampling strategy clearly described?	Sampling strategy & rationale clearly described and justified.	Sampling strategy not clearly described *or* is not fully justified.	Sampling not described.	
5.	Is sampling method likely to recruit all relevant cases? (purposive, theoretical sampling)	Sample includes the full range of relevant, possible cases (more than simple convenience sample) permitting conceptual (rather than statistical) generalisations.	Sampling was purposive but does not include the full range of possible cases.	No attempt made to sample purposively or theoretically, *or* sampling strategy not described.	
6.	Are relevant characteristics of sample given?	Relevant details of the characteristics of sample given.	Incomplete details of sample characteristics given.	No details of sample characteristics given.	
7.	Is rationale for sample size (e.g. data saturation) given?	Gives rationale for termination of data collection e.g. data saturation.	Reasons for sample size implied *or* no firm rationale.	No reason given for sample size.	
	Data collection				
8.	Are methods of data collection clearly described?	Data collection methods are systematic and clearly described allowing an audit trail such that procedures could be replicated.	Data collection methods not clearly described. Difficult to determine if systematic or replicable.	Data collection procedures are not described.	
9.	Is method of data collection appropriate for research question and paradigm?	Data collection methods are appropriate for the research aims and the methodological and analytical framework.	The appropriateness of data collection methods are unclear.	Data collection inappropriate for the aims and methodological framework.	
10	Has the researcher verified the data (e.g. by triangulation)?	More than one method of data collection carried out *or* more than one analyst involved, *or* other methods of verification employed (e.g. member checking or line of questioning during interview).	Unclear whether triangulation or other types of verification used.	No triangulation or other methods of verification described.	
	Data analysis				
11	Are data analysis methods clearly described?	Systematic analytic method clearly described such that procedures could be replicated.	Analytic methods not clearly described.	Analytic methods not described.	

	Criteria	Yes (2/good)	Partial (1/fair)	No (0/poor)	score
12	Are data analysis methods appropriate?	Analytic methods seem appropriate & are well-described.	Analytic methods only partially described and/or some concerns about appropriateness.	Analytic methods not described and/or appropriate.	
13	Are competing accounts/deviant data taken into account?	Account given of negative or deviant cases in the analysis.	Analysis of deviant or negative cases not clearly described.	No account given of negative or deviant cases.	
	Reflexivity				
14	To what extent is the researcher reflective?	The researcher explicitly assessed the likely impact of their own personal characteristics and the methods used on the data obtained.	Possible sources of influence on the data obtained were mentioned, but the likely impact of the influence was not discussed.	No evidence of reflexivity in the report.	
	Conclusions				
15	Are the interpretations and conclusions supported by the data?	The interpretations are clearly described and supported by the data and are evidenced by sufficient participant quotes.	The conclusions are unclear or only partially supported by the data, *or* there is insufficient raw data to support conclusions.	Conclusions are not identified *or* are felt not to be supported by the data *or* conclusions are absent.	

Quality assessment for quantitative studies (Shaw et al., 2009)

Criteria		Yes (2/good)	Partial (1/fair)	No (0/poor)	N/A	Score
Study aims						
1.	Is the hypothesis/aim/objective of the study clearly & sufficiently described?	Easily identified in introduction/method. Specifies: purpose, subjects/target population, and specific interventions/ associations under investigation.	Vague/incomplete reporting *or* some info has to be gathered from parts of the paper other than intro/background/ objective section.	Question or objective not reported/ incomprehensible.		
Study design & sample characteristics						
2.	Is the study design well described & appropriate? *(If study question not given, infer from conclusions).*	Design easily identified, well described and appropriate.	Design and/or study question not clearly described, *or* design only partially addresses study question.	Design does not answer study question *or* design is poorly described.		
3.	Is the method of patient/control group selection described and appropriate?	Described and appropriate. Inclusion/exclusion criteria described and defined.	Selection methods (and inclusion/exclusion criteria) not completely described, but no obvious inappropriateness. *Or* selection strategy likely introduces bias but not enough to seriously distort results.	No information/ inappropriate information provided *or* selection bias which likely distorts results.		
4.	Are the characteristics of patient/control group(s) clearly described (i.e. age range, health characteristic/s)?	Sufficient relevant demographic information. Reproducible criteria used to categorise participants clearly defined.	Poorly defined criteria *or* incomplete demographic information.	No baseline/demographic info provided.		
5.	Were patients/participants randomised to intervention groups?	*If randomisation appropriate:* Evidence of randomisation with a description of the method used (e.g. random number tables, block design).	Randomisation mentioned but method is not (i.e. may be possible that randomisation not true).	Random allocation not mentioned although it would have been feasible and appropriate (and possible done).	Study has no control group i.e. observational/ surveys/case-control. *Or* adequate justification for non randomisation. given.	
6.	*For RCT's only:* Was randomisation/allocation concealed from patients?	Evidence the next allocation was concealed from both parties (recruiter and patient/carer) at the point of consent (e.g. remote randomisation).	Allocation concealment reported but not described.	Allocation concealment would have been possible (and was possibly done) but not reported.	Allocation concealment not possible due to study design (e.g. cluster randomised trial).	
7.	Have the characteristics of patients lost to follow-up been described?	Losses adequately reported & not likely to affect results.	Losses not well reported, but small & not likely to affect results.	No information *or* losses large and likely to affect results.	No patients lost to follow-up.	
8.	Are intervention(s) clearly described?	Defined and reproducible.	Partially defined, but insufficient detail to reproduce design.	Not described.	Not possible/ appropriate – e.g. observational	

	Criteria	Yes (2/good)	Partial (1/fair)	No (0/poor)	N/A	Score
9.	Are the main outcomes to be measured clearly described in the introduction/method?	Defined and measured according to reproducible criteria.	Definition leaves room for subjectivity, *or* not sure (i.e. not reported in detail, but probably acceptable). *Or* precise definition(s) are missing, but no evidence of major problems. *Or* instrument/mode of assessment(s) not reported.	Main outcomes first mentioned in results section. *Or* measures not defined/inconsistent/ poorly defined.		
10	If possible, was an attempt made to blind those measuring the main outcomes of the intervention?	Assessor blind to intervention/study group.	Inadequate blinding: i.e. assessor may have been aware of group participant assigned to.	No attempt made to blind assessor.	Not possible/ appropriate – e.g. observational/ before & after study.	
11	Are population characteristics (if measured & described) controlled for and adequately described?	Appropriate control at design/analysis stage *or* randomised study with comparable baseline characteristics.	Incomplete control/ description. *Or* not considered but unlikely to seriously influence results.	Not controlled for and likely to seriously influence results.		
12	Are the main findings clearly described?	Simple outcome data (e.g. mean/prevalence) reported for all major findings.	Incomplete or inappropriate descriptive statistics.	No/inadequate descriptive statistics.		
13	Are methods of analysis adequately described and appropriate?	Described and appropriate.	Not reported but probably appropriate *or* some tests appropriate, some not.	Methods not described and cannot be determined.		
14	Are estimates of variance reported for the main results?	Appropriate estimates provided (SD/SE, confidence intervals).	Undefined *or* estimates provided for some but not all outcomes.	No information.		
15	In trials/cohort studies, do analyses adjust for different lengths of follow-up, or in case-control studies, is the time between intervention and outcome the same for cases/controls?	Different lengths of follow-up adjusted for (e.g. survival analysis) and adequately described.	Different lengths of follow-up probably adjusted for but not adequately described.	Differences in follow-up ignored.	Cross-sectional design *or* same length of follow-up.	

Appendix 1.3 Extracted Data for HRQoL Review

Ordered by study design

Author (year) Quality score	Aim	Participants (demographics and clinical data)	Methods (Study Design, sampling method)	Overall findings and limitations
Daubenmier et al., 2006 USA 30/24 80% - B1	Assess the impact of lifestyle changes on HRQoL, perceived stress and sexual function in men on the active surveillance programme.	PARTICIPANTS: N=93 DEMOGRAPHICS: **Age** Intervention group (n=44) 64.8 (SD7.1), control group (n=49) 66.5 (SD7.6), **Race** Intervention group 84.1 white, 6.8 black, Latino 4.5, Asian American 2.3 Other, 2.3, Control Group white 96, black 2, Latino 0, Asian American 2, Other 0., **Married living with partner** Intervention Group 66, Control Group 76. **Education** Intervention group 96% college and above, Control group 96% college and above. CLINICAL: **PSA** Intervention Group 6.3 (SD 1.7) Control Group 6.3 (SD 1.7), Gleason score of less than 7 in the biopsy-documented PC group. Localised cancer A randomized consent design was used to limit the amount of lifestyle information the control participants would receive.	DESIGN: Randomized control trial (RCT) (2 groups) TIMEPOINTS: Baseline (before randomisation) and at 12 months after randomization. MEASURES: SF-36, Perceived Stress Scale, University of California Los Angeles Prostate Cancer Index (UCLA-PCI only the sexual function subscale, Lifestyle Index INTERVENTION: Participants asked to eat plant-based vegan diet with 10% of total calories from fat, 3 hours per week of moderate exercise and 1 hour per day stress management practice (stretching, breathing techniques, etc.). After a 1 week residential retreat, weekly support group meetings were held aimed at improving protocol adherence.	At 12months the intervention group made significant positive changes to the lifestyle index compared to the control group. BL intervention group 0.46 (SD 0.3), 12M 1.06 (SD 0.5), BL control group 0.63 (SD 0.4), 12M 0.59 (SD 0.3) (<P=0.005). There were no significant changes in HRQoL between BL and 12M. **At BL** multiple regression analysis indicated that greater lifestyle index scores were related to greater Physical HRQoL scores (controlling for age, education and BMI ($F = 8.71$ $P<0.0001$, $R^2= 0.28$) LIMITATIONS: Study sample was biased in favour of white educated men. Study sample limited to men undergoing active surveillance.
Zhang et al., (2006) USA 21/26 81% – B1	Assess the efficacy of support group and pelvic floor exercise training on HRQoL.	PARTICIPANTS: 196 participants screened for inclusion, 58 participants (30%) were identified as experiencing urinary incontinence during the past week and eligible for the study, N=33 (57%) consented. DEMOGRAPHICS: **Age** control group (mean 60.0, SD 6.9), support group (mean 62.1, SD 5.7) **Race** control group (13 white, 2 African-American), support group (8 white, 6 African-American). **Martial** control group (80% married, 6.7% single, 13.3 divorced) support group (78.6% married, 7.1% single, 14.3% separated), **Education** control group (60% had college associated degrees) support group (47% had college associated degrees).	DESIGN: RCT (2 groups) TIMEPOINTS: Baselines before intervention and 3 months follow-up. MEASURES: Demographics data was collected. No clinical data was collected. McCorkle and Young Symptom Distress Scale (SDS), Medical Outcomes Study Physical Functioning (MOS-PF), Illness Intrusiveness Scale (IIL), Social Adjustment Scale (SAS), Profile of Mood States (POMS), Urinary Incontinence was assessed on a 0-10 V visual analogue scale (VAS) 0 indicated “completely dry” and 10 indicated “completely incontinent”.	There was no difference in global HRQoL scores in either group at 3 months. The support group reported significantly fewer limitations to performing vigorous activities than the control group at 3 months (P=0.026). Correlations were found with greater urinary incontinence was significantly associated with greater symptom distress, more functional limitations, .and higher anxiety and depression (P=0.01) at both baselines and 3 months. LIMITATIONS: Treatment modalities for the study sample were not identified. Limited follow-up of 3 months. Small underpowered study. Cancer-specific HRQoL instrument was not used and data may not have been sensitive to capture a full understanding for HRQoL for the men in this study.

		CLINICAL: T1 – T3 stages, men were screened for urinary incontinence and were asked a single question about bladder control, taken from the Barthel Index. RANDOMIZATION: This process is not clear from the paper.	ATTRITION: N=33 consented, N=3 participants withdrew due changes in work schedules, N=1 dropped out due to dissatisfaction with the assignment to the control group. Total of N=29 participant in results. INTERVENTION: N=29 45 minute biofeedback session (licensed physical therapist) to teach pelvic floor muscle exercises (PFME). After the biofeedback session the participants were randomized to 2 groups, control group (N=15) and social support group (N=14). Social support group instructed to attend for 6 weeks for 2 session per week, over the period of 3 months. Each group consisted of 4-5 participants' and lasted 90-120 minutes facilitated by a licensed health psychologist.	
Galvao et al., (2010) Australia 34/34 100% – B1	Examine the impact of a combined resistance and aerobic exercise programme to improve HRQoL.	PARTICIPANTS: N=97 screened for inclusion, N=57 consented [Excluded N=40, N=19 other commitments, N=10 refused, M=3 unable to walk 300m, N=3 already exercising, N=4 GP refused, N=1 illness] DEMOGRAPHICS: **Age** Intervention group (mean 69.5, SD 7.3), Control group (mean 70.1, SD 7.3), **Race** no data, **Martial** Intervention group (89.7% married), Control group (78.6% married), **Education** Intervention group (51.7% post-secondary education), Control group (71.4% post-secondary education) **Employment** Intervention group (13.8% employed) Control group (7.1% employed). CLINICAL: **Cancer stage** Intervention group (93.1% localized, 6.9% nodal metastasis), Control group (89.3% localized, nodal metastasis 10.7%). **Gleason** Intervention group (mean 7.2, SD 1.6), Control group (mean 7.5, SD 1.0). Hormone therapy. RANDOMIZATION: Randomization was assigned to 2 arms; exercise (intervention), or to the usual care (control). The allocation sequence was concealed from the project co-ordinator and exercise physiologist involved in assigning participants to groups.	DESIGN: RCT (2 groups) TIME POINTS: At baseline and at 12 weeks after the intervention. MEASURES: Whole body, regional lean mass and percent fat measured by DXA. Numerous resistance exercise tests, cardiovascular was assessed by walking 400m, SF-36, EORTC-C30, blood samples (testosterone, PSA, insulin, glucose, CRP, lipids). ATTRITION: N=29 (intervention) of those N=1 discontinued the intervention, N=29 analysed (N=4 had missing data for the EORTC-C30); N=28 (N=1 lost to follow-up, N=28 analysed (N=3 missing data for the EORTC-C30, N=1 missing SF-36) INTERVENTION: The exercise group undertook progressive resistance and aerobic training twice a week for 12 weeks. Sessions were conducted in small groups of one to five participants under supervision from exercise physiologist. Participants were encourages to maintain normal activity and usual diet patterns.	Intervention group showed better score change for general health (P=0.022), vitality (P=0.019) and the physical health (P=0.020) (SF-36). C30 identified better score change role (P=0.001), cognitive (P=0.007), fatigue (P=0.021), Nausea (P=0.025) and dyspnoea (P=0.017) for intervention group. LIMITATIONS: This study had a short follow-up; therefore, it would be unclear whether this intervention would sustainable in the longer term. There were a large number of comparisons made, therefore there is a possibility that some findings occurred by chance.
Carmack Taylor et al.,	Evaluate the efficacy of a	PARTICIPANTS: The total number of participants approached N=1093, well presented flow diagram of recruitment and	DESIGN: RCT (3 groups)	There were no significant differences between HRQoL at 6 or 12 months between the groups (across all the components of the

(2006) USA 26/32 81% – B1	lifestyle programme on HRQoL	screening. N=134 participants consented. N=46 allocated to the Lifestyle programme. N=51 allocated to the Education Support N=37 Standard Care. ALLOCATION: Based on HRQoL, BMI and time on HT. The participants were assigned a 1:1:1 ratio, to ensure equal numbers in the groups. Allocation was conducted by the statistician or data manager. DEMOGRAPHICS: **Age** 69.2 years (range 44.8-89.0). **Race** white 73.1%, Black/African American 20.1%, Other 6.7%. **Employment** 54.4% retired, 40.3% working, 6.7% other. **Education** College degrees or advanced degree 76%. **Marital** married 82.8%. CLINICAL: At baseline participants has been on the androgen-ablation therapy average of 32.7 months. N=12 by orchidectomy and N=122 by HT.	TIME POINTS: Baseline, 6 months and 12 months. MEASURES: Demographic and clinical data, SF-36, Centres for Epidemiological Studies (CES-D), State Scale of the State/Trait Inventory (STAI) Brief Pain Inventory (Short Form), Interpersonal Support Evaluation List (ISEL), 7-Day physical Activity Recall, Stage of Motivational Readiness for Physical Activity, Process for Change of Physical Activity, Decisional Balance for Physical Activity Questionnaire, Physical Activity Self-Efficacy Questionnaire. Six-minute walk test, Body Mass Index (BMI) ATTRITION: Low attrition rates at 6 and 12 months, 6% dropped out, N=5 from the Lifestyle arm, N=2 from the Education Support, N=1 Standard care group. 6 months data was collected in 83% of the sample, 12 months 84%. INTERVENTION: 8 men per group, orientation then for 6 months 16 weekly sessions, and 4 biweekly sessions (1 and half hours). **Lifestyle Programme**: encouraged to take regular exercise, though self-monitoring, goal-setting, overcoming barriers, understanding their caloric intake and exercise expenditure. **Educational Support**: group discussion about diet, PC, side-effects of androgen-ablation and sexuality. **Control group**: Standard Care.	measures). It was hypothesized that social support would improve as a result of the group interventions; the results indicated that social support did not significantly change over the 6 and 12 months follow-up. Overall, this intervention study did not report any significant changes in HRQoL over the 6 – 12 months follll0w-up. LIMITATIONS: Validity and reliability was not reported on all the measures. It was reported that the sample size lacked power to run the study analysis. Bias is possible as a result of the allocation process.
Berglund et al., (2007) Sweden 27/32 84% – B1	Evaluate a psychosocial rehabilitation programme for men with PC.	PARTICIPANTS: N=424 participants were approached, N=228 accepted, N=17 did not return baseline questionnaires resulting in a sample of N=211. DEMOGRAPHICS: **Age** 69 years (range 43-86) **Education** was not evenly distributed across the groups P<0.05. College graduate 24%, Higher certificate 7%, Secondary school 10%, Vocational school 21%, Elementary school 37%. **Marital** married 80%, **Employment** retired 70%. CLINICAL: Within 6 months of diagnosis, WW N=76 (36%), RP N=50 (24%), RT N=21 (10%) HT N=52 (24%), Not known N=14 (7%). Metastases N=42 (20%), Curative treatment	DESIGN: RCT (4 groups) TIME POINTS: Baseline, 2 weeks after intervention, MEASURES: No demographic data. Clinical, HADS, EORTC-C30. ATTRITION: From the N=211, N=23 withdrew because of dissatisfaction of allocation, N=19 no questionnaires at 6 and 12 months. N=158 for the analysis. INTERVENTION: The 3 interventions were made up of seven sessions and groups size varied from 3 to 10	Overall there were no significant difference between men taking part in the interventions and anxiety and depression. The intervention groups did not show any change in HRQoL across the groups, but it was the severity of cancer stage that predicted HRQoL. Men with metastasis generally had a lower HRQoL than men without metastasis on physical function, role function, and financial difficulties (P<0.05). LIMITATIONS: Only 7 sessions might not have been enough to obtain a significant change on outcome. 4 study reduced the statistical power. Selection bias is possible and attrition bias.

		N=76 (36%), no metastases, no curative treatment N=93 (44%).	participants. The scheduling over time was not reported. **Physical training (Phys***):* Led by an experienced PT for 60 minutes physical training followed by a 15 minute coffee break. This programme included physical movement, fitness training, and relaxation, breathing exercises, slow breathing and pelvic floor. **Information (Info***):* Led by a nurse for 60 minutes of information, followed by a 15 minute coffee break. This included giving information about prostate cancer, treatments and side-effects, and actions how to deal with side-effects. Participants had the opportunity to discuss their reactions to having cancer and share their experiences. Demonstration of how to use incontinence or sexual aids, were undertaken as part of this session. **Info + Phys:** this combined both participants has physical training them their information session, the total length was 135 minutes. **Control:** The standard care they received as part of their standard care at their hospital.	
Parker et al., (2009) USA 28/34 82% – B1	Evaluating a stress management intervention study	PARTICIPANTS: N=221 approached, N=164 randomized DEMOGRAPHICS: **Age** Standard care (control group) 60.9 years (SD 5.9), Supportive attention group 60.7 years (SD 7.2), Stress management group 59.8 years (SD 6.9), **Race** standard care white 92%, supportive attention group 70%, stress management group 71% (P=0.01), **Marital** married standard care group **85%,** supportive attention 90%, stress management group 81%, **Education** college and higher standard care group 73%, supportive attention group 85%, stress management group 82%. CLINICAL: T1 to T3 disease. RANDOMIZATION: Use "minimization approach" which results in better balance of demographics in the groups. The characteristic used was age <60, >60 years, partner (living with partner of not), type of surgical procedure (nerve sparing or not). The data collection assistant was blinded to the participant randomization.	DESIGN: RCT (3 groups) TIME POINTS: I month before RP, 1 week before RP, 6 weeks after surgery, 6 and 12 months after surgery. MEASURES: Demographic and clinical data. Profile of mood states, Impact of Events Scale, SF-36, and UCLA-PCI. ATTRITION: N=164 baseline assessment, N=5 dropped out because of a lack of time to participate, left N=159 for randomization. INTERVENTIONS: **Stress management (SM):** 2, 60-90 minutes individual sessions with a clinical psychologist and stress management guide, booster session in the morning of surgery and 48 hours after surgery. **Supportive attention (SA):** 2, 60-90 minutes individual sessions with a clinical psychologist focussing on psychosocial and medical history in a semi-structured format. Psychologist used empathy and reflective listening skills. Participants also had 2 booster sessions in the morning before surgery and 48 hours after	There were significant differences in mood shortly before and after surgery. However, at 6 and 12 months there were no significant differences between the groups (all P>0.05). Participants in the SM had higher physical function scores than men in the SC (P=0.0009) at 12 months No other significant differences for group comparisons. Prostate specific HRQoL: urinary function (P=0.0001), urinary bother (P=0.0001), urinary limitation (P=0.0001), sexual function (P=0.004) worsened from baseline to 6 weeks, 6 months after surgery, but began to improve at 12 months after RP. In summary SM group had short-term improvement for mood disturbance. Men in the SM have reported better physical function than other groups at 12 months. There were no difference between groups for the prostate cancer-specific HRQoL. LIMITATIONS: Sample biased in favour of white, educated and married men. Existing co-morbidities were not reported and may have influenced the results. Bias is possible in randomization.

			surgery. **Standard Care (SC):** This group had no meetings with a clinical psychologist and only received standard care.	
Northouse et al., (2007) USA 27/32 84% - B1	A dyad study assessing the impact of the family based intervention.	PARTICIPANTS: N=429 participants were approached, N=263 patient-spouse dyads were groups together based on stage of illness and treatment, than participants were randomized to either the control group or intervention group (selection rate of 68.7%). DEMOGRAPHICS: **Age** participants 63 years (mean, SD 9.1), partners 59 (mean, SD 9.7), **Race** white 84%, **Education** mean 16 years of education both participants and partners. CLINICAL: NEWLY DIAGNOSIED: 65% were in diagnosed phase; 60% RP, 40% RT. BIOCHEMICAL RELAPSE: 14% of the sample had biochemical relapse; 50% were being managed under observation, 50% HT, ADVANCE STAGE: 21% in advance (Mets) stage; 36% treated with HT, 64% receiving HT and chemo RAMDOMIZATION: The data collection nurses were randomized to the stratification. The type of randomization was not reported.	DESIGN: RCT (2 groups) TIME POINTS: Baseline (before intervention), 4, 8, 12 months after intervention. MEASURES: Demographic and clinical data, SF-12, FACT-G, FACT-P, Appraisal of Illness or Appraisal of Care giving Scales, Brief Coping Orientations to Problems Experienced Scale, Lewis Cancer Self-efficacy Scale, Communication assess with the Lewis Mutuality and Interpersonal Sensitivity Scale, Symptoms Scale of the Omega Screening Questionnaire, EPIC, ATTRITION: N=263, 235 (90%) completed 4 months assessment, N=218 completed (83%) both 8 and 12 months follow-up. INTERVENTION GROUP: Supportive-educational intervention called FOCUS that was initially piloted in breast cancer. It consisted 3 X 90 minutes home visits and 2 X 30 minutes telephone calls sessions spaced 2 weeks apart and deliver between baseline and 4 months. All sessions were aimed at family involvement, optimistic attitude, coping skills and uncertainty reduction and symptom management. All delivered by intervention nurses trained by the PI of the study. CONTROL GROUP: Received standard care from hospital.	There were no differences in HRQoL in either study group. There were also no difference in disease-specific HRQoL. Partners reported the most positive benefit from the intervention, better physical HRQoL at 8 and 12 months compared to their partner controls. A clear point is that partners of men with prostate cancer should be included in intervention studies in the future giving the clear benefits from these reported findings. LIMITATIONS: The results are limited to men with partners; men without partners were not included in this study. Bias is possible in randomization.
Monga et al., (2007) USA 28/32 87% - B1	Assess the impact of exercise in improving fatigue and HRQoL	PARTICIPANTS: N=35 participants approached, N=30 participants consented. DEMOGRAPHICS: **Age** intervention group 68 mean (SD 4.2) years, control 70.6 mean (SD 5.3) years. **Race** white intervention group N=3, black N=7, Hispanic N=1, control group white N=4, black N=5, Hispanic N=1, **Marital** married intervention N=7, control N=7 (there are no significant differences in clinical demographics between the groups).	DESIGN: RCT (2 groups) TIME POINTS: before and after RT. MEASURES: Demographic and clinical data, Cardiovascular fitness, flexibility, strength, fatigue, FACT-P and FACT-G, BDI (Depression) ATTRITION: N=30 participants consented, N=5	Intervention group (stand and sit test, flexibility, physical functioning scale, physical well-being scale, social well-being, FACT-P) showed statistical improvements from pre-RT to post-RT. Control group reported significantly worse post-RT scores on the physical function scale and the social well-being scales compared to pre-RT scores. LIMITATIONS: Small N in the groups.

		CLINICAL: All the participants received 7 to 8 weeks of RT, 68-70Gy.	withdrew, N=4 discontinued, leaving N=21 reported in this paper. Missing data was not reported. INTERVENTION: Exercise intervention group N=11 (structured exercise 3 time per week for 8 weeks) before RT in the morning, consisting of a 10 minutes warm-up, 30 minutes aerobic session and 5-10 minutes cool-down. Control group N=10 usual care (unaware of the control arm).	
Culos-Reed et al., (2007) Canada 23/24 95% – B2	Assess impact of exercise intervention on HRQoL	PARTICIPANTS: N=121 participants were approached, N=63 ineligible, N=27 refused, N=31 consented to take part. DEMOGRAPHICS: **Age** 64.8 mean (SD 9.8) years, **Education** college and higher 51.6%, high school and less 48.4%. **Employment** retired 51.6%, employed 32.3%, sick leave 12.9%, other 3.2%. **Marital** married/partner 90.3%. CLINICAL: Time since diagnosis month 33.9 mean (SD 42.1). Break down of clinical data not reported, i.e. cancer stage, previous treatments in addition to current HT.	DESIGN: Before and after intervention study (1 group, no control) TIME POINTS: Baseline (consent), immediately after the intervention programme at 12 weeks, and 4 months follow-up after intervention. MEASURES: Demographic and clinical data, EORTC-C30, Fatigue Severity Scale, Leisure Score Index of the Godin Leisure Time Exercise Questionnaire) Cardiovascular and strength, BMI height, waist to hip ratio. ATTRITION: N=31, N=18 completed the 4 months follow-up (58%). There was no significant difference between responders and non-responders. 81% attended 5 or 6 sessions, 16% attended 4 sessions. INTERVENTION: 12 week theory-based intervention design to promote daily activity. An individualized programme was provided by a certified fitness professional (week 1), in a group based-session. In an effort to foster social support, group based structured exercises sessions were every 2 weeks (1, 3, 5, 7, 9, 11) of the 12 weeks programme.	Significant positive improvement from T1 to T2 for physical activity (P<0.01), fitness parameters (P<0.01), and increases in role functions (P<0.03) and fatigue (P<0.05) of the EORTC-C30. Global QoL increased but did not reach significance (PP=0.13). 4 months fatigue severity scores increased, and global QoL scores decreasing significantly to below baseline levels (P<0.05). LIMITATIONS: Small sample size, lack of a control group to evaluate the changes reported. Physical actives relied on self-report measure questionnaire; methods such as a pedometer reading would have provided an objective measure.
Pendo et al., (2006) USA 31/32 96% – B1	Assess the efficacy of intervention study on HRQoL	PARTICIPANTS: N=592 contacted, N=271 screened, N=169 refused, N=339 excluded, leaving N=93 enrolled in the study. DEMOGRAPHICS: **Age** 65.5 mean (SD 7.6), **Education** years of education 12 mean (SD 3.5) years, **Race** 62% Cuban/American, 15% Colombian/American, 10% Central American countries, 4% other south American counties, 8%	DESIGN: RCT (2 groups) TIME POINTS: Baseline (before intervention) and 12-13 after baseline assessment. MEASURES: Demographic and clinical data, Charleston Co-morbidity Index, FACT-G, EPIC, All participants were	Control Measures – higher income was associated with greater total well-being (r=.23, P<0.06), lower co-morbid conditions (r =-.35, P<0.01) were associated with greater physical well-being, and a higher educational level was associated with greater emotional well-being (r=.20, P=.09). These variables were controlled for at relevant analyses of HRQoL. Controlling for relevant co-variants, the intervention group condition significantly predicted greater

		did not identify their country of origin. Mean years living in USA was 27 mean (SD15.5) years. CLINICAL: Mean months since diagnosis was 16 (4.9) months. The average number of co-morbidities was 2 (SD 2). N=32 RP, N=39 RT all localized disease.	screened with the Structured Clinical Interview for DSM-IV/non-patient edition (to exclude individuals suicidal, panic attacks, psychosis, substance dependence, etc.) ATTRITION: N=53 allocated to intervention, N=1 yet to complete assessment, N=1 missing, N=9 withdrawn. N=40 allocated to control, N=3 yet to complete assessment, N=5 missing, N=2 withdrawn. CONTROL: Groups of 4-6 participants were invited to attend a half-day psycho-educational seminar tailored to Spanish speaking men. 4 single 1 hour sessions with tailored stress management/relaxation skills delivered by clinical psychologist. INTERVENTION: 10 week Cognitive-Behavioural Stress Management (CBSM) intervention, groups met once per week, for 2 hour sessions, including stress management (coping strategies, assertiveness training, etc.), and relaxation training (breathing exercises, deep breathing, etc.).	physical well-being, emotional well-being, sexual-functioning, and total well-being after the 10-week intervention period. CBSM improved HRQoL for men treated for localized PC. LIMITATIONS: This study has a short follow-up; it is possible that the positive effects of this intervention would not be found at longer follow-up time points. Small sample size. This study used a screening for major cognitive impairment and is limited to localized disease, thus it limits the generalisabilty to more physical and psychologically compromised individuals with PC.
Fransson, 2008 USA 27/28 - 96% -B3	To examine urine toxicity and HRQoL in localized PC participants with age matched controls	PARTICIPANTS: Participants N = 27 treated with radiotherapy for PC, Controls N = 37. DEMOGRAPHICS: **Age at time of 15 years follow-up** participants mean 78.1 (range 62-87), controls mean 77.3 (range 64-89) P=0.376 CLINICAL: Tumour dose (Gy) 64.8 (range 62.0-67.8). T-classification T1b 3, T2 21, T3 3.	DESIGN: Prospective longitudinal with matched controls. . The control match group were individuals without localized PC living in the same geographical location. TIMEPOINTS: All the participants included in the study answered questionnaires at 4, 8, and 15 years follow-up. MEASURES: Prostate Cancer Symptoms Scale (PCSS), EORTC C30 . ATTRITION: **4 year follow-up study** Participants N = 181, Controls N = 141, **8 year follow-up study** Participants N = 88, Controls N = 98, **15 year follow-up study** Participants N = 41, Controls N= 69. **Reponses rates 15 years** Questionnaires sent out Participants N = 41, Controls 69, Questionnaires completed Participants 29 (71%) Controls 41 (59%), Excluded from the analysis Participants N = 2, Controls N = 37. Total for the analysis Participants N = 27 and Controls N = 37.	Participants reported a limitation in daily activities caused by urinary symptoms at 4, 8, 15 years compared with aged matched controls at a significance level of (<P = 0.05). There were no differences in HRQoL stratified by hormonal and non-hormonal treatment in the patient group. 15 years follow-up only the role function scale on HRQoL differed between the 2 groups at 15 years, this was lower for the patient group (<P = 0.05). General domain of HRQoL remained stable over the 15 year apart from the role function. Participants had worst urinary, pain, diarrhoea in comparison with age matched controls 15 years after RT. LIMITATIONS: No data was presented about the BL data (pre-treatment) on the Participants or the Controls. Small N. 15% of the 181 were analysed in this results of this study. There was no evaluation of disease-specific HRQoL to evaluate bowel symptoms a known after effects of RT.

Smith et al., (2006) Australia 20/22 91% – B3	To compare HRQoL for men with PC with age match controls	PARTICIPANTS: Participants N=1642, controls N=507 DEMOGRAPHICS: **Age** PC participants (mean 61.2 years, range 37 to 69 years) Controls (mean 61.2, no range). There was no further demographic data available suitable for extraction. CLINICAL: N=981 had RP (60%), N=289 had either RT and RT and hormones (18%) and N=200 was on active surveillance. Inclusion: Aged 70 years or less, localized disease, with no evidence of metastasis, no more than 12 months after diagnosis.	DESIGN: Prospective longitudinal with match controls. Controls randomly assigned electoral register matched by age and postcode. TIME POINTS: Baseline (mean 3 months after diagnosis, range 1 to 12 months), and in the majority of case after primary treatment had begun, 1, 2, 3 years follow-up after baseline, and 1, 2, and 5 years for the control group. MEASURES: Limited demographic data collected, clinical data, Los Angeles Prostate Cancer Index (LA-PCI), SF-12, International Prostate Symptoms Score (IPSS), Total co-morbidity score. ATTRITION: Participants PC groups N=1642 completed baseline, N=1599 completed 1 year, N=1530 completed 2 years, N=1493 completed 3 years. Control groups N=507 completed baseline, N=433 completed 2 year, and N=380 completed 5 year.	The mental component was similar across all the groups. Men on hormone therapy had lower physical score than the controls at baseline and 3 years. RP participants had highest incontinence at 1 and 3 years. Bowel problems/function was similar at baselines for PC participants and controls. Radiotherapy participants reported most bowel problems. Sexual function at baseline for the controls N=109 (22.3%) and N=128 (27.6%) reported they were unable to obtain an erection firm enough for intercourse. 3 years, nerve sparing RP N=307/494 (67.9%), RP 379/476 (86.7%), BT N=20/58 (36.4%), RT N=72/123 (67.9%) were impotent. After controlling for relevant co-variants hormone therapy group had the worse sexual function. LIMITATIONS: The baseline assessment was undertaken after treatment started therefore interpretation of changes in HRQoL is difficult. Different numbers in both groups that may have been problematic for analysis.
Anger et al., (2007) USA 16/20 80% – B3	To compare PC participants access to free health care and men currently on the waiting list for free healthcare	PARTICIPANTS: Uninsured men with PC we enrolled into a free Low Income Uninsured Assess for Men, California Initiated Programme (IMPACT). Group 1, Enrolled, N=83; 79% recruitment rate). Group 2, Waiting list, N=83, 74% recruitment rate. DEMOGRAPHICS: **Age** Group 1 (mean 59.0 years, no SD reported), Group 2 (mean 59.2, no SD reported). **Race** Group 1 (white 21.7%, Hispanic 50.6%, black 18.1, other 9.3%) Group 2 (white 18.1%, Hispanic 56.6%, black 14.5%, other 18.4%). CLINICAL: Different cancer stages	DESIGN: Prospective longitudinal with matched pairs. Group 2 was matched by stage, age and race (P=1.00, P=0.88, and P=0.81 respectively). TIME POINTS: Group 1 baseline at enrolment, 6 months and 18 months after enrolment. Group 2 not clear from the paper, only at enrolment. Compared HRQoL at enrolment and assignment onto the waiting list. MEASURES: RAND Medical Outcomes Study Short Form-12 (SF-12) for HRQoL, Medical Outcomes Study Mental Health Index (MHI-5) for emotional well-being, McCorkle and Young's Symptoms and Degrees of Distress in Participants with Cancer Scale (SDS) for cancer distress symptoms, Perceived Self-efficacy in Patient-Physician Interactions Questionnaire (PEPPI) for perceived self-efficacy in interacting with physicians, UCLA Prostate Cancer Index Short Form, prostate cancer-specific HRQoL.	Significant difference between the groups from the SF-12 was the general health subscale Group 1 (enrolled mean score 48) Group 2 (waiting list mean score 40) P=0.05. The SD and t value not reported. Group 2 (waiting list) also reported significantly less self-efficacy than group 1 (enrolled) PEPPE (score difference of 2.5; P=0.005). enrolled men have less symptom distress and higher self-efficacy than men not enrolled in the programme. Overall, HRQoL was not significantly difference between the groups. LIMITATIONS: Cross-sectional design does not enable causal relationships to be identified. Limited clinical and demographic data, i.e. other co-morbidities that may influence HRQoL in this patient group. Possibility for recruitment bias.

			ATTRITION: Only cross-sectional data reported for matched pairs N=83 group 1, N=83 groups 2, no missing data.	
Jayadevappa et al., 2005) USA 20/22 91% - B3	Compare HRQoL in men <65 years old with PC to age matched controls.	PARTICIPANTS: N=40 participants, N=40 age matched controls DEMOGRAPHICS: **Age** PC group mean 57.7 (SD 5.2), control group mean 59.3 (SD 3.3) P=0.1347, **Race** PC group white 91.4%, control group 91.2% P=0.9704, **Education** PC College or more 75.53%, control 82.35 P=0.3803 CLINICAL: No statistical difference was found between the groups in urinary frequency, bladder infections, and blood in the urine, tiredness and co-morbidity. Participants mostly received RP as primary treatment alone 93.75%, the remained received RP + HT/or RT.	DESIGN: Prospective longitudinal with matched controls. TIME POINTS: Baseline (before treatment), 3, 6, 12, 24 months after treatment. Control group only completed baseline. MEASURES: Demographic and clinical, Charleston co-morbidity Index (CHI), Medical Outcome Study Short Form, UCLA-PCI. ATTRITION: N= 40 men with PC and N=40 Controls. There were no reports of missing data in this study for questionnaire follow-up.	Physical role and function, role emotional and vitality decreased at 3 months, improved back to pre-treatment levels at 24 months for participants. Urinary function improved at 12 months and at maintained 24 months and Bowel function recovered at 3 months for participants. Sexual function worsened at 24 months compared to baseline. Predictors of 24 months HRQoL subscales: **Sexual function**: married, co-morbidities, BL sexual function. **Urinary function**: married, education, TNM stage, **treatment Bowel function**: married, co-morbidities, treatment. **Social function**: married, income, co-morbidities, baseline social function. **Bodily pain**: age, married, income, co-morbidities, treatment **General health**: married, co-morbidity, TNM stage, baseline general health LIMITATIONS: Small sample size. The comparison made between the participants and the control was cross-sectional, thus not causal relationships could be tested.
Thong et al., (2009). Netherlands 19/22 86% - B3	Compare HRQoL for long-term PC men	PARTICIPANTS: N=71 AS and N=71 RT groups DEMOGRAPHICS: **Age** AS N=70 >60 years, N=1<60 years, RT 71> 60 years (no difference P=0.46). **Marital** Married AS 55%, Single 14% no significant relationship, Married RT 54%, no significant relationship 16% (No difference P=0.92). **Working** AS not working 63%, working 5%, RT not working 65%, working 5%. CLINICAL: **Years since diagnosis** AS 7.9 mean (SD 1.3), RT 7.7 mean (SD 1.1) (no difference P=0.33). All PC participants were T1 or T2 disease.	DESIGN: Matched Controls (controls are men on active surveillance) TIME POINTS: Mean follow-up 7.9 (years) after diagnosis. MEASURES: Demographic and clinical data, Dutch version SF-36, Dutch validated Quality of Life – Cancer Survivors questionnaire, EPIC, Dutch Sexual Activities Module, Charleston co-morbidity Index. ATTRITION: N=142 completed the questionnaire, no missing data was reported.	No significant differences found in general HRQoL between both AS and RT groups, including physical and psychological well-being. RT groups have more symptoms than the AS groups, significantly poorer/lower bowel function. No significant differences between urinary and urinary bother scores for both groups. RT group significantly worse sexual function than AS group LIMITATIONS: Due to the cross-sectional design, the casual relationship between variables is not explored. The results are limited to 2 treatment modalities, AS and RT. There is the possibility of recruitment and responder bias as this data was not reported.
Korfage et al., (2006) Netherlands 18/20 90% – B3	Assess HRQoL for men with PC and healthy controls	PARTICIPANTS: Part of a previous PC study cohort, N=63 were approach to take part; some participants withdrew, moved house, died, and loss of contact details. N=53 men were interviewed. N=53 participants, N=52 controls DEMOGRAPHICS: **Age** participants 67.1 years (SD 4.3), controls 62.7 years (SD 4.3) P<0.001.	DESIGN: Matched pairs. (controls < than 74 years, with no previous benign prostate hyperplasia or PC) TIME POINTS: Not identified in PC participants trajectory. MEASURES: Interactive Internet Questionnaire 1) respondents level of functioning, 2) ranking of health	No different in either group for evaluations of 5 common health states after the treatment of PC, no difference in the evaluation of urine, bowel and sexual dysfunction between the 2 groups. LIMITATIONS: No demographic data was reported this would have introduced possible confounding variables. No co-morbidity data was reported on the control group was this could have introduced a potential bias in their valuations of the patient state.

		CLINICAL: Different treatment modalities.	descriptions, 3) evaluations of Man 1 to Man 5 by time-trade offs (TTO). ATTRITION: No missing data reported.	
Krupski et al., (2005) USA 18/22 81% – B3	Compare HRQoL for low-income men with PC, and age-match controls	PARTICIPANTS: N=277 were approached of which N=181 (79%) consented. Non-recruits were more likely to be older and have progression of disease (P<0.05) DEMOGRAPHICS: **Age** 60.5 mean years, **Race** Hispanic 52.5%, black 17.7%, white 22.6%, other 7.2%, **Education** high school and less 93.9%,. CLINICAL: All participants with non-metastatic disease. Limited clinical data reported.	DESIGN: Cross-sectional – matched to age controls TIME POINTS: At enrolment of the IMPACT programme. MEASURES: Demographic and clinical data, Charleston Co-morbidity Index, SF-12, ATTRITION: N=181, N=136 were reported for this analysis	HRQoL all domains participants scored <50 points below the age-matched normative sample. (P<0.0001). Predictors of HRQoL: **Physical component**: Hispanic. **Mental component:** co-morbidity. **Urinary function**: RP. **Sexual function**: age, ethnicity, RP. **Bowel function**: Hispanic. General and prostate cancer-specific HRQoL was negatively affected in low-income men with PC, compared to older men without prostate cancer. LIMITATIONS: Treatment data was not reported the study does not control for clinical variation between participants. Cross-section design therefore the causal relationships cannot be identified. Time of since diagnosis or treatment completion is not controlled for can introduce bias.
Queenan et al., (2008) Canada 18/18 100% – B3	Assess the impact of social support on HRQoL for men with PC	PARTICIPANTS: N=513 participants met the inclusion criteria. Random sample of N=250 were selected, and N=234 were mailed out. DEMOGRAPHICS: **Age** 55-64 12,7%, 65-69 28.7%, 70-74 32.5%, 75-82 26.1%., **Marital** married/partner 85.9%, **Education** College and above 39.5%, CLINICAL: All men were treated with RT. 12-72 months after treatment localised/locally advanced cancer.	DESIGN: Cross-sectional random samples. TIME POINTS: 1 time point MEASURES: Demographic and clinical data, Functional Support Index derived from the Multiple Outcomes Study Social Support Survey, structural support was measured using questions from the National Populations Health Survey, EORTC-C30. ATTRITION: N=234, N=169 returned the questionnaire (84%). .	12.6% (moderated problem), 68.2% (big problems) with sexual function, 19% had a moderate/big problem with urinary function and 17% reported moderate/big problem with bowel function. General domains of HRQoL were unaffected. Predictors of HRQoL were co-morbidity, urinary, bowel, sexual, hot flashes, weight changes, and current hormone therapy. LIMITATIONS: Cross-section nature, and the causal relationship between social support and HRQoL cannot identified. Selection bias is possible
Jayadevappa et al., 2006 USA 26/26 100% – B3	Assess HRQoL for men with PC	PARTICPANTS: N=115 (>65years) with prostate cancer DEMOGRAPHICS: **Age mean:** 69.5 (SD4.5) years, RP 67.4 (SD 1.5) years, RT 71.3 (SD3.5) years (p<0.001): **Race** Caucasian RP 97.2%, RT 65.3% African-American RP 2.8%, RT 34.7%: **Education** High school education and less RP 27.8%, RT 49% College degree and more RP 72.2%, RT 51% CLINICAL: RP (n=69), RT (n=46)	DESIGN: Prospective longitudinal. TIME POINTS: 1-2 weeks after study enrolment before treatment, 3, 6, 12 months after treatment MEASURES: Short Form-36, University of California Los Angeles Prostate Cancer Index (UCLA-PCI), Client Satisfaction with Care (CSQ-8), Demographic (age, ethnicity and health insurance data was collected). Charleston co morbidity score (CHS). ATTRITION: N=115, n=107 3months, n=105 6months, n=102 12months.	The RP group at baseline higher physical function, role physical, social function and general health compared to RT group. Bodily pain was lower in the RT group than the RP group. Cancer-specific HRQoL, the RP group reported higher scores on urinary function, bowel function and bowel bother at baseline. RT group reported higher sexual bother at baseline. RP group reported improvement after an initial decline at 3M, and had values similar to baseline by 12M across HRQoL domains. RT group did not show an improvement over the baseline values at 12M for general HRQoL. Cancer-specific HRQoL at 12M for RT had better urine and sexual function, but worst bowel function compared to the RP group. Predictors of higher 12M HRQoL: Caucasian, married, higher education, lower TNM classification.

				LIMITATIONS: Sample biased in favour of white men, and results limited to RT and RP. Selection and attrition bias are possible.
Feigenberg et al., 2005 USA 24/ 23 - 96% – B3	Assess HRQoL for men treated with BT	PARTICPANTS: 98 participants with localised PC treated with BT only. DEMOGRAPHIC: **Age** <70 n=65, >70 n=33: **Race** White n=90, Black n=5, Asian n=2, Other N=1: **Marital Status** Married/in relationship n= 81, Single/divorced/Widowed n=9, Unknown n=8: **Education** Grade 1-8 only n=3, Some High School n= 11, High School Graduate n=22, Attended College n=49, Unknown n=13 CLINICAL: T1c or T2a, all treated with BT	DESIGN: Prospective longitudinal TIME POINTS: Baseline before BT, 3M, 6M, 9M and 12M after BT MEASURES: Functional Assessment of Cancer Therapy for Prostate Cancer (FACT-P) and the FACT-G (General measure for HRQoL). A higher overall score indicated a better quality of life. The IPSS, modified version of the Sexual Adjustment Questionnaire ATTRITION: 101 participants enrolled. 3 participants were eligible, 1 because of concurrent malignancy, 1 hip prosthesis and PSA performed before registration >30. Total of 98 participants included for the analysis.	The percentage of men who reported the ability to have an erection decreased from 73% at baseline to 58% at 3M and remained stable at 12M, 59% of men. Urinary incontinence increased at 14% at 6M and returned to BL level at 9months, and then improved below BL to 1% at 12M. 78% participants at 12M state they can achieve an erection with or without assistance), almost 50% has a worse sexual function at 12M. LIMITATIONS: Large proportion of missing data was reported (unclear how this was managed in analysis). Sample biased in favour of white married men.
Wickstrom Ene et al., 2006 Sweden **23/24 - 96% B3**	To explore HRQoL for men treated by RP	PARTICIPANTS: Recruited from 2 hospitals 3 weeks before surgery. 183 participants were approached and 155 participants consented (85%) DEMOGRAPHICS: **Age** 63.1 years (range 43-73), **Marital status** 91% were married, **Education** about 36% have elementary education. CLINICAL: Participants had to wait >3 months for their operation. **Pain relief at baseline**; Continuous epidural analgesia (EDA) N=90, Intrathecal analgesia (ITA) N=50, Systemic analgesia N =15	DESIGN: Prospective longitudinal. TIMEPOINTS: Demographics and the SF-36 was completed at recruitment, the HADS was completed the day before surgery. Participants post-operative experience was evaluated 24, 48,72 hours. 3 months after the operation participants were mailed the SF-36, HADS and questions asking about their pain experience. MEASURES: SF-36, HADS, Demographic form, ASA, pain treatment, length of stay in hospital. ATTRITION: N=155 consented into the study, N= 140 completed the 3 month follow-up (N=15 lost to follow-up)	Correlations between high post-operative pain in hospital and the length of stay in hospital (<P=0.01). Discharge N=40 reported moderate/severe pain after discharge, skin incision pain, abdominal pain were the most commonly reported. Patient with high scores for depression decreased from N=13 preoperatively, to N=11 at 3 months follow-up. 3 months after surgery 84% (60%) of the participants has reached baseline HRQoL components except for vitality. The physical functioning and role-physical functioning had significantly decreased (<P=0.001) when compared with baseline. 3 months after surgery anxiety and depression were negatively correlated with all components of the SF-36 (<P=0.01). LIMITATIONS: Recruitment bias may have been possible.
Ficarra et al., 2005 Italy 22/24 - 92% B3	Evaluate HRQoL for men treated by RP	PARTICIPANTS: N=150, N=105 (70%) consented, N=30 excluded (28.5%) because of delays in returning their questionnaires. N=75 participants (71.5%). DEMOGRAPHICS: **Age** 64.4 (SD 5.6, range 51-72) years, **Race** all were Caucasians, **Marital status** 89% were married, 7%	DESIGN: Prospective longitudinal. TIMEPOINTS: Baseline before surgery, 3, 6 and 12 months follow-up. MEASURES: SF-36, urinary incontinence was evaluated	The baseline values for all the SF-36 components overlapped by 12 months. Predictors of lower general HRQoL at 12 months: >65 years, lower educational level, and extracapsular extension of the primary tumour. 3 months after surgery N=15 (20%), N=9 at 6 months, and N=6 at 12 months were incontinent. Men with no ED had significantly higher scores for general health perceptions,

		unmarried, 1% separated and 3% widowers, **Education** 60% had no secondary school diploma, 31% had a diploma, 9% had a college degree. CLINICAL: Localised cancer all treated by RP.	using and institutional developed measure. International Index of Erectile Function. ATTRITION: no reported	emotional well-being, role limitations due to physical health problems and energy/fatigue. HRQoL scores were lowest at 3 months, with a gradual improvement over the 12 months follow-up. LIMITATIONS: Urinary function did not report reliability or validity. This study did not report participant attrition and selection bias is possible.
Glabraith et al., (2008) USA 23/34 - 95% - B3	Explore HRQoL for couples dealing with PC.	PARTICIPANTS: N=216 DEMOGRAPHICS: **Age mean** 67.8 years (SD was not reported), the oldest patient group was watchful waiting age mean 73 years, and the youngest patient group was those receiving surgery age mean 61 years. **Race** 86% of participants all were Caucasians, **Marital status** participants reported being married for an average of 34.8 years, **Education** 74% had some form of college education. CLINICAL: Participants had localised disease for stage 1 and stage 2. The treatment that men underwent watchful waiting (N=12), Surgery N=39), conventional radiotherapy (N=8), Mixed beam radiotherapy (N=48) and proton beam radiotherapy (N=109).	DESIGN: Prospective longitudinal. TIMEPOINTS: Participants and partners completed questionnaires just before treatment, 6 months, 12 months and 18 months after treatment. MEASURES: Demographic and clinical data was collected. Quality of Life Index (QLI), SF-36, Dyadic Adjustment Scale (DAS) which is designed to evaluate the quality of marriage and satisfaction with the relationship. ATTRITION: N=216 couples, 6 months N=198 couples, 12 months N=187 couples, 18 months N=161 couples (overall attrition rate was 26%).	Before treatment patient group reported better physical role functioning, emotional role functioning, mental health, less pain than their partners. However partners reported higher better general health than the men. 6 months partners reported better HRQoL, but men reported better mental health at 6 months. 12 months partners had better HRQoL and general health than participants at 12 months. Men continued to have better mental health than their partners at each follow-up. LIMITATIONS: Findings of HRQoL did not identify the differences in individual treatment modalities, with uneven participant numbers in each treatment modality group, thus making statistical comparison difficult to interpret. Attrition rate of 26%, bias could be possible in the couples that dropped out who had different experiences with diagnosis' and treatments. Selection bias is also possible.
Roeloffzen et al., (2009). USA 22/22 100% – B3	Assess HRQoL overtime for men treated by brachythera py	PARTICIPANTS: N=127 DEMOGRAPHICS: **Age mean** 65 years (SD not reported), range 50-78. No further demographic data was presented. CLINICAL: T1 or T2 treated by BT	DESIGN: Prospective longitudinal. TIMEPOINTS: Before treatment, 1 month, 6 months, 1 year, and 6 years after treatment. MEASURES: Clinical data. RAND-36 generic health survey, EORTC-C30 and EORTC prostate specific module (PR-25) ATTRITION: N=127 before treatment, 1 months, 6 months and 12 months after treatment. All participants were re-contacted median follow-up 6.4 years N= 102 completed the questionnaire, of the 25 non-responders 15 participants had died, 7 were lost to follow-up and 3 refused to complete the questionnaire.	(SF-36) Worse physical functioning 6 years compared to baseline, better mental health and less pain levels at 6 years compared to baseline. C30 physical functioning worsened at 6 years. Emotional functioning, insomnia and pain levels improved at 6 years. Urinary symptoms/problems, bowel function and sexual function got worse at 6 years compared to baseline. Predictors of 6 years urinary symptoms: hormonal treatment, initial PSA level. Bowel function: prostate volume. Older age was associated with diminished sexual activity at years. Age, hormonal therapy, initial PSA level were predictors of poorer sexual functioning. LIMITATIONS: Recruitment bias may have been possible, social and demographic data was not collected in this study, this may have influence HRQoL.

Diefenback et al., (2007) USA 22/22 100% – B3	Explored decisional regret and its associations with HRQoL.	PARTICIPANTS: N=1370 participants were contacted and N=986 consented and completed and return baselines questionnaire (72% up-take into the study). DEMOGRAPHICS: **Age** (mean 65.57 years, SD 7.62, range 39-82 years), **Race** 91.8% were Caucasian, **Marital** 82.5% were married, **Education** 24.1% had either college education or post-graduate education. CLINICAL: T1 or T2 stage disease, undecided about treatment options. All participants had completed their treatment at 6 months follow-up. N=437 (52.1%) radiotherapy, N=220 (26.3%) brachytherapy, N=136 (16.2%) prostatectomy, N=39 (4.7%) watchful waiting, N=6 (0.7%) hormone therapy.	DESIGN: Prospective longitudinal. TIMEPOINTS: Baseline at diagnosis, 6 months and 12 months. MEASURES: Demographic and clinical data, to reduce questionnaire burden only 3 items from the Sexual Adjustment Questions (SAQ) were used, only 3 items from the American Urological Association (AUA) symptoms index, and only 2 items from the Decision Regret Scale (DRS). ATTRITION: N=986 completed baselines questionnaire, N=923 completed at 6 months, and N=838 completed 12 months questionnaires. Attrition bias: results showed that Caucasian, married, and retired participants were more likely to stay in the study (P=0.01).	Participants reported increasing sexual problems across all the groups at baseline, 6 and 12 months. Overall men reported less urinary problems compared to sexual function problems. Participants' perceptions of sexual and urinary bother were strong predictors of decisional regret; with decisional regret highest in the RP group, and HRQoL is impaired due to treatment side-effects. LIMITATIONS: Majority of participants (70%) were recruited for a radiology department, thus making a treatment bias possible for the highest number of participants opting for RT. This study did not use the full measures of the questionnaires to reduce questionnaire burden, Cronbach's alpha = ranged from .60 to 74 for the items. The study is limited to participants with localised disease; decisional regret may be different for men with more advance or recurrent disease.
Guedea et al., (2009) Spain 18/22 82% – B3	Compare HRQoL for 3 treatments modalities (RP, BT and radiotherapy) localised PC	PARTICIPANTS: N=304 DEMOGRAGHICS: **Age** N=114 RP (mean 63.9, SD 5.8), N=134 Conformal Radiotherapy (mean 68.8, SD 5.7), N=56 BT (mean 67.5, SD 5.9). No further demographics were collected. CLINICAL: T1 or T2 disease. Men treated by RP, BT or radiotherapy.	DESIGN: Prospective longitudinal TIME POINTS: Before treatment, 1, 3, 6, 12, and 24 months. MEASURES: No demographic data was collected. Clinical data, SF-36, FACT, Expanded Prostate Cancer Index Composite (EPIC). ATTRITION: Attrition was not reported.	Participants receiving RP were significantly younger, PSA level was significantly higher in the radiotherapy group than the other groups and BT group has the lowest mean Gleason Scores. Hormone therapy usage was more frequent in radiotherapy group. 1 month irritative and obstructive urinary symptoms were substantially worst in all 3 groups with recovery 3 months, except for the BT which was worst. Only 15% across all groups reported irritative urinary symptoms at 24 months. RP had the worst urinary incontinence from 1 to 24months follow-up compared to other groups. RP had substantially worse sexual function compared to other treatments. No significant changes were found for the SF-36 physical or mental component across the 3 groups over the 2 year period. Noticeable side-effects or brachytherapy was urinary irritation, RP incontinence and sexual function had a most negative impact. There were no pronounced noticeable effects for the radiotherapy group. LIMITATIONS: Potential for attrition and recruitment bias is present. The treatments were not randomized therefore there were several between group differences at baseline.
Diefenback et al., (2008)	Assess the impact of	PARTICIPANTS: N=1370 contacted, N=986 consented and completed baseline measures (approx 70% up-take to the	DESIGN: Prospective longitudinal	Employed participants were more likely to report worries of cancer recurrence, longer expected survival time and better

USA 22/22 -100% – B3	age on HRQoL for men with PC	study). DEMOGRAPHICS: **Age** older patient group >68 years N=192, Middle age group <68 years N=199, **Marital** Older group 82.8% married, Middle group 52.8%., **Education** Older group 26% >college, Middle group 22.6>college, **Race** Older group 95.3% Caucasian, Middle group 87.4% Caucasian. CLINICAL: N=500 (50.7%) RT, N-215 (25.5%) BT, N=164 (16.9%) RP and N=62 (6.3%) active surveillance.	TIME POINTS: Before treatment, 6 months, and 12 months after treatment. MEASURES: Demographics and clinical data, Impact Event Scale, Decisional Regret Scale, 2 items for Worry of Cancer Recurrence, 1 item for Subjective Life Expectancy, FACT-P. ATTRITION: Analysis limited to N=391 all EXRT participants and completed the 3 follow-up time points.	functional well-being compared to unemployed. Married men had better functional and social well-being compared to unmarried men. Middle aged group had lower psychological distress and better emotional and physical well-being. Decisional regret was associated with lower levels of emotional, functional, physical and social well-being. Positive associations were found with Gleason scores and psychological distress, worries about cancer recurrence. LIMITATIONS: Treatment bias, as large majority recruited from radiation oncology department. Unfortunate not to report finding on other treatment groups and change over time.
Davidson et al., (2007) Canada 22/22 100% – B3	Explored changes in HRQoL for men undergoing RP and decisional regret.	PARTICIPANTS: N=155 were approached, N=130 (84%) completed baseline data collection. DEMOGRAPHICS: **Age** (mean 62.05, SD 6.02) years, **Education** 71% had more than high school education, **Marital** 85% married, **Employment** 56% either in part-time or full-time employment **Race** all participants were Caucasian. CLINICAL: PSA 82% of men <10ng/mL, Gleason 88% between 3-6. N=39 (30%) of study participants received neoadjuvant hormone therapy	DESIGN: Prospective longitudinal. TIME POINTS: Before RP and I year follow-up. MEASURES: Demographical and clinical data, Decisional Regret Scale, Control Preferences Scale, EORTC-C30 and EORTC-PR-25, Sexual Health Inventory for Men (SHIM) ATTRITION: From the N=130 before surgery, at year 1 N=25 (16%) did not return questionnaire. A comparison was made between responders and non-responders no significant difference in age, education or sexual function at baseline.	Sexual function significantly worsened at 1 year. Before RP N=99 (76%) reported having none or mild ED. At 1 year N=76 (77%) reported having moderate/severe ED. Men who received hormone therapy has the worse sexual function. Change overtime C30: worse physical functioning 1 year compared to BL. Improved emotional functioning and social functioning at 1 year. PR-25 significant improvement in treatment related symptoms at 1 year. Pain levels , worsened from before RP to 1 years. Anorexia improved at 1 year. Financial difficulties were significantly higher at 1 year compared to baseline. LIMITATIONS: The number of men who received nerve-sparing surgery and prescribed medication for ED was not documented, i.e. self-management may have influenced HRQoL. Sample biased in favour of white educated men
Gellekom et al., (2005) Netherlands 20/22 91% - B3	To assess changes in HRQoL in men who received BT.	PARTICIPANTS: N=127 participants consented. Data was not reported on the number of participants approached. DEMOGRAPHICS: No demographic data was reported. CLINICAL: Cancer stage T1 and T2.	DESIGN: Prospective longitudinal TIME POINTS: Before BT, 1 month, 6 months, 1 year, 2 years after implant. MEASURES: No demographic data was reported. Clinical data, EORTC-C30 and EORTC-PR-25, RAND-36 health survey, IPSS. PARTICIPANTS: N=127, N=103, N=117, N=120, N=115 and N=87 completed questionnaires (Before BT, 1 month, 6 months, 1 year, 2 years after implant) respectively.	Summary, Global HRQoL was worse 4 weeks after BT treatment compared with other time points, but returned to pre-treatment scores at 1 year. EORTC-C30 role functioning worsened at all time point compared to baseline. Emotional functioning significantly improved overtime at all time points and exceeded pre-treatment values at 2 years. Pain scores significantly worsened overtime at all time points and never regained pre-treatment scores at 2 years. PR25- Urinary symptoms significantly worsened at all time points and were problematic at 2 years. Urinary problems were most problematic 1 month after BT. Bowel problems significantly changed worsened at all time points compared to baseline scores. Sexual function was worse at all time points compared to baseline.

				LIMITATIONS: No demographic data was provided as this may have influenced HRQoL, in addition to other co-morbidities. Potential for recruitment bias.
Ash et al., (2007) UK 13/18 72% – B3	Assess changes in HRQoL in participants receiving BT overtime.	PARTICIPANTS: N=150 were invited to take part, N=127 consented and returned baseline data (84.7%) DEMOGRAPHICS: No demographic data reported. CLINICAL: Neoadjuvant hormone therapy and BT. The hormone therapy was discontinued after BT. N=67 (58%) received hormone therapy.	DESIGN: Prospective longitudinal. TIME POINTS: Before BT, 6 weeks, 6 months, 10 months, 18months, 24 months. (Based in clinical follow-up time points). MEASURES: No demographic or clinical data. International Prostate Symptom Score (IPSS), Expanded Prostate Index Composite (EPIC) PARTICIPANTS: N=150, N=116 at all time points (77%) response rate. Differences between responders and non-responders were not reported.	Urinary function worsened at 6 weeks and urinary function gradually improved over the first year. 6 weeks there was considerable urinary irritation and obstruction and some incontinence. Bowel function at baseline was not high in this patient group, at 6 weeks bowel symptoms worsened from BL 92.2 summary score, to 6 weeks after BT to 84.7 summary score, most common symptom loose stools. Sexual functions significantly lower for men treated by hormone therapy. LIMITATIONS: No measure of general HRQoL. Selection and attrition bias are possible. No demographic data and no co-morbidity data as possible confounders.
White et al., (2008) USA 14/24 58% – B3	Assess HRQoL of men with locally advanced PC.	PARTICIPANTS: Total 13, 740 men in the CaPSURE database, N=608 had locally advanced PC, N=151 completed the questionnaires at all the time points. (25%). DEMOGRAPHICS: **Age** (mean 68, range 44-91). No further demographics reported. CLINICAL: N=31 RP, N=12 cyrotherapy, N=26 BT, N=82 HT.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (not clear what baseline is), 1, 2, 3 years after treatment. MEASURES: Age, clinical data, SF-36 and the UCLA-PCI. ATTRITION A comparison between responders and non-responders was not reported for all treatment groups.	Age had a significant impact on all aspects of the SF-36, in addition to urinary function/bother and bowel function. Mental well-being (SF-36) gradually improves over time and exceeded baseline values. Urinary and sexual problems also significantly worse at 1, 2, 3 years compared to baseline. Urinary function gradually improved at 1, 2, 3 years compared to baseline. No significant change over time for bowel dysfunction, this could be explained as no participants received RT in this reported paper. LIMITATIONS: Selection and attrition bias are possible. The usages of nerve sparing surgical techniques are not identified, as previous research identifies significant differences in HRQoL using this technique. HRQoL of men received RT was also not reported.
Choo et al., (2006) USA 21/24 87% – B3	Examine the effects for combined treatment in participants with T3 cancer on HRQoL	PARTICIPANTS: N=78 DEMOGRAPHICS: **Age** 61years old (median) at time of RP. CLINICAL: N=48 had undetectable PSA levels 3 months post-op, N=30 has detectable PSA. All men were treated with radiotherapy (median time 4.2 months) post-op. HT was started within 2 weeks of receiving radiotherapy for 2 years. N=13 of the N=78 terminated HT prematurely, at a mean of (13 months).	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 3 weeks in to RT, 6 weeks in to RT treatment, 2 months at the start of HT, 6 months HT, 10 months, 14 months, 18 months, 22 months. MEASURES: Age, clinical, EORTC-C30 + PR25. ATTRITION: N=78, N=70 completed the 2 year follow-up, N=8 had incomplete follow-up data. All the follow-up data was included in an intention to treat analysis.	Bowel dysfunction significantly worsened at the end of radiotherapy and improved at 6 months. Urinary dysfunction was maximal at the end of RT. The increase in urinary dysfunction lost statistical significance at the 2 months visit, and there was no significant change from baseline function. Fatigue, pain, insomnia and diarrhoea statistically worsened from baseline though out the follow-up. None of the global or functional domains reached any statistical significant change from baseline. N=13 of the N=78 terminated HT prematurely, at a mean of (13 months). The most common reasons reported was hot flushes in N=5, fatigue in N=2, gynecomastia, elevated liver enzymes, deep vein thrombosis, arthralgia, hypertension, and a rash, N=1 respectively.

				LIMITATIONS: Selection and attrition bias are possible.
Buron et al., (2007) France 19/20 95% – B3	Compares HRQoL for participants treated with either BT or RP.	PARTICIPANTS: N=435 DEMOGRAPHICS: **Age** RP (mean 62.7, SD 6.0), BT (mean 65.2, SD 6.3), P=0.0003. **Education** RP low 39.3%, middle 27.9%, high 32.8%, BT low 32.0, middle 32.0, high 36.0, P=0.0083. CLINICAL: N=308 BT, N=127 RP. RP 86% treated with retropubic, 14% treated laparoscopic. N=9 (7%) received adjuvant RT.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), end of treatment, 2, 6, 12, 18, 24 months after hospital discharge. MEASURES: Demographic, clinical, EORTC-C30 and PR25, cost measures. ATTRITION: N=435 , RP 41%, BT 65% completed the full follow-up at 24 months. Overall response rate baseline 92%, 6 months 72%, and at 24 months 58% for all the men in the study. Men in the BT group were more likely to return the questionnaires than the RP group.	BT group showed an initial decrease in global HRQoL between T1 and T2 (-5.8 points, P<0.0001) this was the largest decrease. At subsequently follow-up the global HRQoL change was not significant. RP group also showed an initial decrease in global HRQoL from baseline to the end of treatment (-18.0, P<0.0001), and recovered rapidly between 2 and 6 months which was no longer significant subsequent follow-up time points. Better role function was in favour of BT group. No significant changes in any other subscales of the C30 for both groups. Urinary incontinence problems were more frequently reported in the RP than the BT at all time points. Urinary symptoms, faecal incontinence and rectal bleeding were more frequently reported in the BT than the RP group. Erectile function was at its worse for the RP at 6 months, 88% of sexually active men reported poorer erectile function than at baseline, compared to 50.8% of BT. Problems persisted at 18 months RP 83.3%, BT 45.8%, reported poor erectile function. Treatment for impotence was more common in the RP 32% vs. 12.5% BT group. LIMITATIONS: An RCT would have potentially controlled for confounders that may have entered in the analysis. Different questionnaire response rate for BT and RP, may have introduced potential bias. In addition, the studies aim was to compare both BT and RP, however, a larger proportion of the BT had had hormone therapy, from existing evidence HT has a worsening effect on HRQoL.
Chen et al., (2008) USA 22/22 100% - B3	Assess HRQoL for men with localized prostate cancer.	PARTICIPANTS: N=522 DEMOGRAPHICS: **Age** RP (median 60, range 46-74), NSRP (median 59, range 46-72), NNRP (median 62, range 50-74), RT (median 69, range 51-82), BT (median 64, range 47-77). **Education** College and above RP 90%, NRP 88%, NNRP 94%, RT 76%, BT, 87%, **Marital** married 91%, NRP 89%, NNRP 94%, RT 83%, BT 83%, **Race** white RP 99%, NRP 99%, NNRP 100%, RT 95%, BT 91%. CLINICAL: RP N=127: NRP N=74, NNRP N=53, RT N=190, BT 82.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline before treatment, 3, 12, 24, 36 months after treatment. MEASURES: Demographic and clinical data, Index of Co-Existent disease, PCIS. ATTRITION: N=522, N=84 withdrawn participation before the 36 months follow-up, N=438 (84%) response rate. Comparisons were made between responders and non-responders and no statistical difference reported. Only N=409 results are reported based on the most common treatments RP, RT and BT.	RP and BT men were significantly younger and had less co-morbidity than the RT group. All treatment groups reported worsening sexual dysfunction over time. Bowel problems were different based on treatment modality, RP did not lose function, whereas RT did. Urinary incontinence developed in more than twice as many surgical participants as RT and BT participants at 36 months. Summary, participants' baseline function significantly influences the magnitude of change HRQoL at follow-up. LIMITATIONS: This study has a large proportion of white educated participants that reduces generalisabilty. It is possible for recruitment bias.

Caffo et al., (2006) Italy 21/22 95% – B3	Assess HRQoL in participants with localized PC treated with BT.	PARTICIPANTS: N=206 approached, N=29 refused, N=30 did not receive the baseline questionnaires because of organisation failure. N=147 in the follow-up study. DEMOGRAPHICS: **Age** 67 (median, range 52-77) **Race** not reported, **Marital** married N=124 (84.5%), **Education** 47.6% only went to primary education, 19.3% middle school, 23.5% high school, 7.5% university, 2.1 unknown. CLINICAL: all men T1-T2 treated with BT. HT N=70 (47.3%) received treatment.	DESIGN: Prospective longitudinal. TIME POINTS: I week before BT, 1 month, 1, 2, 3,4 years after treatment. MEASURES: Clinical and demographic, HRQoL measure (the title not reported, but they report that this is a validated tool) used in PC studies. ATTRITION: N=147, only N=16 questionnaires were lost to follow-up. A comparison between responders and non-responders were not reported.	Urinary function worsened at 1 month after treatment and gradually improved overtime, final follow-up was not significantly different from baseline. Bowel function significantly worsened after BT but improved at 1 year. N=74 declared regular sexual activity, N=70 no activity at baseline. Reported predictors of better sexual function were age ≤67 years, not receiving HT, and those who did not have PVD. No significant difference was observed for general physical well-being, mental well-being, social relationships, and physical anatomy at 1 month after treatment. LIMITATIONS: Authors identify caution is required when interpreting the findings because the men may view BT as a modern technique that avoided the symptoms of the well-known traditional treatments, therefore their optimistic view may influence their responses. Attrition bias is possible
Brar et al., (2005) USA 22/24 91% - B3	Assess HRQoL in men PC living in poverty.	PARTICIPANTS: N=184, N=41 excluded because of metastatic disease, N=5 with second primary cancer, leaving sample N=138 for the analysis. DEMOGRAPHICS: **Age** <60 N=38 (28%), 60-65 N=79 (57%), >65 N=21 (15%), **Race** white N=35 (25%), Latino N=73 (53%), African American N=22 (16%), other N=8 (6%), **Marital** married/living with partner N=85 (62%), significant other but not living together N=17 (12%), no significant other N=36 (26%), **Monthly income** $0 N=85 (62%), $1-1500 N=91 (66%), >$1500 N=11 (8%), **Education** High school non graduate N=58 (42%). CLINICAL: HT N=7 (5%), RP N=78 (57%), WW N=8 (6%), RT N=45 **Co-morbidities** 0-1 N=81 (62%), ≥2 N=49 (38%)	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (3 months after enrolment of the IMPACT programme) and 6 months follow-up. MEASURES: Clinical and demographic data, UCLA-CPI short form-15, SF-12, Medical Outcomes 5-item study Mental Health Index. ATTRITION: N=138, N=85 (61%) did not complete all the measures. Comparisons were made between responders and non-responders no significant difference was found in the demographic or clinical data.	Controlling for age, race, baseline HRQoL measures and treatment effects, participants with higher Gleason scores experienced more negative effects on HRQoL. Men with less than high school education had the greatest improvements in mental well-being. Bowel and urine function improved from baseline to 6 months. Prostate cancer-specific HRQoL components showed an improvement at follow-up in all domains except for sexual function. LIMITATIONS: Limited follow-up of 6 months, potential for selection bias.
Dalkin et al., (2005) USA 19/22 86% - B3	To assess HRQoL from a single surgeon for participants being treated with RP.	PARTICIPANTS: N=176 men enrolled DEMOGRAPHICS: **Age** (mean 62.9, range 35-79). No further demographic data reported. CLINICAL: **PSA** (mean 8.5 ng/mL, range 0.5-60), **Gleason** (5-6 = 67%, 7 = 27%, 8-10 = 6%)	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before surgery), 1 and 2 years after treatment. MEASURES: Age, clinical data and SF-26 and the UCLA-PCI. ATTRITION: N=176, N=158 (90%) complete 1 year follow-up, and N= 105 (82%) completed the 2 year follow-up.	There were no significant changes in general components of HRQoL at year 1 or year 2. Men reported being pad free from urinary incontinence pad-free in 82% at years 1, and 89% at year 2. N=22 used it as a safety liner, N=6 truly needed a pad at 1 year. Younger men (<60 years) and having NRP did not have any better urinary function. Sexual function worsened at 1 and 2 years. LIMITATIONS: Selection and attrition bias are possible and limited demographic data provided and therefore limited the generalisabilty of the findings.

Couper et al., (2009) Australia 22/24 91 - B3	Compare anxiety, depression and HRQoL in men PC.	PARTICIPANTS: N=211 DEMOGRAPHICS: **Age** (mean 66.15, SD 8.26, range 43-92), **Marital** married/living with partner 78.3%, **Occupation** employed 36.8%, Retired/unemployed 63.2%. CLINICAL: WW N=61, RP N=38, HT N=56, RT N=193 [at time 1]. The distribution of treatments for the full N=211 is not reported.	DESIGN: Prospective longitudinal. This study used WW as the control group. TIME POINTS: Baseline (before treatment), after treatment and 1 year after treatment. MEASURES: Demographic and clinical data. SF-36, Brief Symptoms Inventory (BSI-53) to measure anxiety and depression. ATTRITION: Of the N-211, N=193 completed time 1 data, and N=172 (89.1%) completed time 2 data. The difference between responders and non-responders was not reported.	Time 1 HT, RP and RT experienced worse HRQoL than the WW group. The HT groups had significantly worse depression scores than the WW group. Role physical function was significantly lower at time 1 for 3 treatment groups in comparison to the WW group. Vitality scores in the HT and RT groups were also significantly worse at time 1 compared to the WW group. 1 year the HT group had significantly worse scores on anxiety, depression, physical function, role physical function, pain, general health and vitality. 3 groups treatment groups experienced initial worse HRQoL compared to the WW group, however the HT group continued to report worse HRQoL at 1 year and an increase in anxiety and depression. LIMITATIONS: This paper acknowledges that recruitment in clinics introduces the possibility of recruitment selection bias, as not all men with PC in the community have the opportunity to be recruited. Attrition bias is also possible. There was no measure of prostate cancer-specific HRQoL.
Sanda et al., (2008) USA 22/22 100% – B3	Assess HRQoL in men and their partners treated for localized prostate cancer.	PARTICIPANTS: N=1201 participants and N=625 partners consented. DEMOGRAPHICS: **Age** (median age 63 years, range 38-84), **Race** white RP 91%, white RT 82%, BT white 85%, **Education** College graduate and above RP 62%, RT 52%, BT 55%, **Marital** married RP 87%, RT 77%, BT 70%. Partners of who 99% were female, **Age** (median 59 years, range23-89) and younger than participants P<0.001. CLINICAL: RP=602, RT N=292, BT N=306. BT group N=35 received combination BT and RT/and also HT. RT N=90 received RT + HT.	DESIGN: Prospective longitudinal. TIME POINTS: Patients: baseline before treatment, 2, 6, 12, 24 months after treatment. Partners: 2, 6, 12, 24 months. MEASURES: Demographic and clinical data. Expanded Prostate Cancer Index Composite, Service Satisfaction Scale for Cancer Care (SCA), PARTICIPANTS: N=1201 N=112 did not complete the follow-up for the following reasons; N=12 died (from other causes not related to PC), N=84 withdrew, N=16 missing data. There was not reported comparison between responders and non-responders.	Key predictors of HRQoL stratified by treatment group: **sexual function**: RP group: age, PSA level, nerve sparing technique. RT group: age, prostate size, neoadjuvant HT. BT group: age, PSA score. **Urinary incontinence**: RP group: age, black race. RT group: PSA level. BT group: neoadjuvant HT, combination with RT. **Urinary irritation or obstruction:** RP group: prostate size. RT group: prostate size, neoadjuvant HT. BT group: prostate size, PSA level, clinical stage, neoadjuvant HT. **Bowel dysfunction**: RP group: co-morbidity. BT group: Gleason score above 7. **Vitality**: RP group: obesity. RT group: obesity, prostate size, neoadjuvant HT, co-morbidity. BT group: prostate size, age, neoadjuvant HT, combination boost with RT. Urinary incontinence was at its worse by 2 months after surgery and gradually improved in most patients, whereas symptoms of urinary irritation/obstruction improved after treatment in the RP group. In the RT group urinary symptoms resolved at 12 months and improved over baseline score at 24 months. The BT group had the worse urinary irritation at all the follow-up time points compared to baseline (P=0.001). BT and RT reported significantly worse bowel function compared to baseline, but recovered at 1 year. Sexual function was better in participants that received NRP, compared to those men who did not. RT group sexual function

				was worse for men who received HT compared to those who did not. Worsening reports of sexual function from patients were reflected by distress from partners RP 44%, RT 22%, BT 13% by partners. LIMITATIONS: selection and attrition bias are possible and limits the generalisabilty of the findings.
Gacci et al., (2009) Italy 19/24 79% – C1	Assess HRQoL in PC men who are disease free at 5 years.	PARTICIPANTS: N=367. DEMOGRAPHICS: **Age** mean 64.8 (median 66, range 47-77). CLINICAL: **PSA** mean 14.6 ng/mL, TNM stage T2 N=222 (60.5%), pT3a N=77 (21%), pT3b N=59 (16%), T4 N=9 (2.4%). NRP was performed in N=125 (34%).N=76 (20.7%) received adjuvant HT.	DESIGN: Prospective longitudinal only one time point reported TIME POINTS: N=307 5 year follow-up (mean 95.5 months, range 61 to 156), N=60 the follow-up was 60 months. N=60 had a follow-up at 5 years, N-146 had follow-up 7-7 years, N=81 follow-up 8-9 years, N=80 follow-up 10 years and more. MEASURES: Age and clinical data, Italian version of the UCLA-PCI. ATTRITION: N=367, no missing data reported	Associations of HRQoL: **Urine function**: age, PSA, TNM stage, Gleason, HT. **Sexual function**: age, follow-up time, PSA, TNM stage, Gleason, HT. Age, clinical variables, and HT were associated with worsening function and bother. LIMITATIONS: This study lacked baseline HRQoL for a comparison of outcomes at 5 years. No general HRQoL measure was used. Demographic data for this patient group was not reported and selection bias possible that reduced the generalisabilty of the findings..
Van de Poll-Franse et al., (2008) USA 21/22 95% - B3	Assess the impact of cardiovascular disease (CVD) on HRQoL in men with PC.	PARTICIPANTS: N=830 (Cancer of the Prostatic Strategic Urological Research Endeavour (CaPSURE). The recruitment rate 74%. DEMOGRAPHICS: **Age** stratified by Total Illness Burden Index (TIBI): none N=293 (mean 63.7, SD 7.8), TIBI Mild N=293 (mean 64.9, SD 7.8), TIBI Moderate N=51 (mean 66.9, SD 7.3), TIBI Severe N=51 (mean 67.2, SD 7.1): P<0.0001. **Race** white TIBI no 93%, TIBI Mild 94%, TIBI 97%, TIBI Moderate 97%, TIBI Severe 88%: P=0.10. CLINICAL: Men had stage T1-T3 disease, treated with RP, BT or RT.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (pre-treatment), 6, 12, 18, 24 months after treatment. MEASURES: Demographic and clinical data. RAND 36 Health Survey, UCLA- PCI, Total Illness Burden Index (TIBI). ATTIRTION: Of the N=830, N=78 had 2, N=216 had 3, and N=536 had 4 completed questionnaires. Differences between responders and non-responders were not reported.	At BL generic and disease-specific HRQoL was negatively associated with increasing CVD P<0.0001 in all sub-components. HRQoL scores were worse for men treated with RT. Men with moderate or severe CVD had the worse SF-36 physical and mental scores, and worse bowel function at all-time points (P=0.05). Men with severe CVD also experienced a slower recovery for physical functioning and sexual functioning. In summary, men with PC who have CVD can experience lower HRQoL and a slower return to baseline over time. LIMITATIONS: The presence of TIBI was only checked at baseline; therefore, the co-morbidity of disease may have change overtime for the study participants. Recruitment and attrition bias are possible.
Fransson et al., (2009) Sweden 21/24 87% – B3	Assess HRQoL in men with localised PC in participants receiving RT	PARTICIPANTS: N=72, N=54 (77% response). DEMOGRAPHICS: **Age** RT (median 77 years, range 54-87), WW (median 78, range 65-88). No further demographics reported. CLINICAL: T1 or T2, N=27 (RT) and N=27 (WW)	DESIGN: Prospective longitudinal. TIME POINTS: 4 years after diagnosis and 10 years. MEASURES: Age and clinical data, EORTC-C30, PCSS. ATTRTION: Missing data occurred in RT 3% and WW 4%, no differences were found between responders and non-	Cognitive score change for the RT (difference of -11.3; P=0.034) indicating a worsening function. In the WW group the physical functioning (difference of -11.5; P=0.041) worsened over the follow-up time period also. RT group fatigue was worse over time. WW group worsening insomnia and financial difficulties over time. N=5 (19%) in the RT group, N=2 (7%) in the WW group used pads to manage urinary incontinence at 10 years. No

	and WW.		responders.	significant difference was found in bowel function for the groups. No significant difference in erectile function in either group over time. LIMITATIONS: Small N. This study lacked baseline data, thus caution is given for interpretation of the study findings.
Galbraith et al., (2005) USA 23/24 95% – B3	Assess HRQoL in men with localised PC	PARTICIPANTS: Participants N=192 approached, N=137 completed (71%); Partners N=126 approached N=104 completed (83%). DEMOGRAPHICS: **Age** participants (mean 70 years) with WW participants being the oldest and RP being the youngest (F=5.1, P<0.001). **Marital** 80% participants married. **Education** 71% attended college and more. **Race** white 86%, hispanic 6%, black 5%, Asian 2%, undisclosed race 1%. CLINICAL: WW N= 21, RP N=39, convention RT N=18, Proton beam RT N=21, Mixed beam RT N=37, low dose mixed beam RT N=25, high dose mixed beam RT N=31.	DESIGN: Prospective longitudinal. TIME POINTS: 2.5, 3.5, 4.5, 5.5 years after treatment. MEASURES: Demographic and clinical, Quality of Life Index, SF-36, Southwest Oncology Group Prostate Treatment-Specific Symptoms Measures, Dyadic Adjustment Scale. ATTRITION: N=20 died (N=4 from prostate cancer), N=6 from other illnesses such as cardiac disease and other cancers, N=10 from unknown causes.	HRQoL decreased for all groups over the 4 years of follow-up. At 5.5 years WW groups had lowest HRQoL scores. Men in the low dose mixed beam RT group had better physical role function than men in the RP group. Vitality decreased in all groups. Social functioning score differed in all the groups, however the WW reported the worse scores after treatment. General health decreased in all the groups over the follow-up. Low dose mixed beam RT groups reported better general health, fewer GI symptoms than the high beam mixed dose RT and the WW group. Urinary symptoms increased over the study for all the groups, but WW group reported the most urinary symptoms. Sexual dysfunction was problematic for all groups at each time point. 7% reported that their erections were adequate for intercourse, 66% reported that their erections were not adequate to be able for penetration. Only 27% received treatment for erectile dysfunction. LIMITATIONS: No baseline data reported in this patient group that make change over time and interpretation of the findings difficult. Selection bias is possible.
Zavala et al., (2009) USA 22/24 91% - B3	Assess the impact of spirituality on HRQoL in men with metastatic PC.	PARTICIPANTS: N=144, N=101 consented DEMOGRAPHICS: **Age** <60year 31%, 60-65 38%, >65 30%. **Race** white 20%, Latino 62%, African-American 10%, other 8%). **Martial** in a significant relationship 71%, no significant relationship 29%. **Education** high school <46%, high school graduate 41%, College graduate 14%. CLINICAL: **Co-morbidities** 0-1 79%, >2 21%. Gleason >6 97%, **Treatments** RP N=16, RT N=10, HT N=83, Chemotherapy N=20, Ketoconozole and hydrocortisone N=5.	DESIGN: Prospective longitudinal. TIME POINTS: At enrolment to IMPACT, and 6 months follow-up. MEASURES: Demographic, clinical data, FACIT-Sp, UCLA-PCI, SF-12, PEPPI, Charleston Score (co-morbidities). ATTRITION: N=101, N=1 was excluded because an administrative form was not completed, N=88 completed the questionnaires, N=2 did not complete the spirituality questionnaire. Leaving total sample in this study N=86.	Ethnicity was a predictor of dichotomised high and low spirituality scores . Highest spirituality scores were in less-educated, Latino and African-American men. Spirituality was significantly associated with physical, mental component, bowel function, SF-12 pain and self-efficacy. In sum, reported higher spirituality scores were associated with higher HRQoL domains. LIMITATIONS: Small N, High percentage of Latinos, the sample did not have an even spread of ethnic individuals, thus bias may have been possible and limits generalisabilty.
Stephens et al., (2006)	Assessing HRQoL in	PARTICIPANTS: Trial data. N=862 participants were enrolled, N=843 were randomised in 25 centres in the UK, Australia	DESIGN: Prospective longitudinal.	Sexual function score worsened during the short time on receiving HT. No improvement was found for urinary function over time.

UK 20/22 90% – B3	participants receiving neoadjuvant hormone therapy before RT.	and New Zealand. N=290, N=319 and N=290 had data available to answer the hypothesis in this paper. DEMOGRAPHICS: **Age** (median 67, range 63-71). No further demographic data reported. CLINICAL: Stage T1 to T3, PSA <50ng/mL, no previous PC treatment. Participants received androgen suppression using LHRH at 4 weekly intervals in conjunction with an anti-androgen to prevent 'flare' initially.	TIME POINTS: Before HT treatment and before RT. MEASURES: Age, clinical and UCLA-PCI, PACT-P. ATTRITION: All data was available.	Participants' physical well-being declined whilst being on HT. Overall, men's ability on HT showed the greatest decline in their ability to maintain sexual function. LIMITATIONS: There was no control group to establish the full extent of treatment effects such as a control group match base age, pre-existing co-morbidity and socio-economic variables. .
Sullivan et al., (2006) USA 21/24 87% - B3	Assess changes in HRQoL in men with Hormone Refractory PC (HRPC).	PARTICIPANTS: Data for the paper was collected as part of a phase III trial. N=809. DEMOGRAPHICS: **Age** median age 72 years. CLINICAL: Median survival time was 491 days, the medial time to disease progression was 85 days, the median time to bone pain was 86 days. N=690 had bone metastasis, N=97 soft tissue metastasis, N=22 no metastasis.	DESIGN: Prospective longitudinal TIME POINTS: Baseline study entry, 4 weeks, and every 12 weeks. MEASURES: Age and clinical data, EORTC-C30, FACT-G and the FACT-P, FACT Advanced Prostate Symptom Index. ATTRITION: Before baseline data collection N=29 died, N=262 had disease progression. Baseline and 12 weeks HRQoL compliance was 95-96% and 88% to 90% for the FACT, and EORTC, respectively.	In participants with HRPC, Gleason scores, PSA, Bone alkaline phosphatase, lactate dehydrogenase and performance scores (Karnofsky Performance scale) were all significant predictors of mortality. When baseline HRQoL was added to the model, scores greater than the median was a significant predictor of mortality. Better baseline HRQoL scores predicted better survival, time to disease progression and pain prognosis than those with worse baseline HRQoL scores. It appears that greater deterioration in HRQoL scores is prognostic for rapid disease progression. LIMITATIONS: No demographic data was presented in this study, and limits the generalisabilty of the findings.
Lev et al., (2009) USA 21/22 95% – B3	Assess HRQoL for men treated with RP, Intensity Modulated Radiotherapy (IMRT) + High Dose Radiation (IMRT + HDR), or IMRT + BT.	PARTICIPANTS: N=159 DEMOGRAPHICS: **Age** mean 63.8 (range 42-82 years). **Race** white 86%, **Education** approx 50% college graduate. **Employment** approx 50% employed. CLINICAL: RP N=49, IMRT+HDR N=49, IMRT +BR N=61	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment) 6, 12 months after treatment. MEASURES: Demographic and clinical data, Prostate Symptom Self Report (PSSR), Symptoms Checklist 90 Revised Anxiety Subscale (SCL-90-R Anxiety Subscale), PSS, The Centre of Epidemiological Studies Depression Scale (CES-D), Strategies Used by Participants to Promote Health (SUPPH), FACT-P, ATTRITION: The present study was based on N=150, attrition was not reported, in full, however there was no significant difference between the responders and non-responders (the results not reported).	**Predictors of Global HRQoL at 6 months**: Age, urinary symptoms, bowel function, sexual function, depression, physiological efficacy, performance efficacy, baseline HRQoL. **Predictors of Global HRQoL at 12 months:** Urinary symptoms, stress, depression, coping, baseline HRQoL, race and being married. HDR group reported higher bowel symptoms scores than men who received RP baseline, 6 and 12 months. BT group reported higher bowel symptoms at 6 and 12 months compared to the RP group. Urinary symptoms were worse of BT at 6 and 12 months compared to the RP group. LIMITATIONS: There was not control/report of co-morbidities which may have biased the findings. The possibility for recruitment bias is also possible.
Latini et al., (2006)	Evaluate the impact of	PARTICIPANTS: N=1248 were divided into 2 groups N=117 who had RP with diabetes mellitus (DM) and N=1131	DESIGN: Prospective longitudinal.	Urinary function was the only significant difference for men with DM compared to men without DM. Sexual function also showed a

USA 20/22 90% - B3	diabetes in men receiving RP for PC in relation to reported of HRQoL.	without DM. DEMOGRAPHICS: **Age** RP no DM <65 years (66%), >65 years (34%), RP + DM <65 years 53%, >65 years (47%) P<0.01, **Race** White RP no DM 93%, White RP + DM 84%, P<0.01, **Education** RP no DM college graduate 52%, RP + DM 40%, P<0.01. **Marital** married RP no DM 95%, RP + DM 91% P+0.15. CLINICAL: Stage T1 to T3, had RP as monotherapy, PSA <10ng/mL, Gleason <7.	TIME POINTS: Baseline (pre-treatment) and 12 months after treatment. MEASURES: Demographic and Clinical data, UCLA-PCI PARTICIPANTS: Total sample N=1248 no attrition reported.	decrease in mean scores in both groups. Bowel function was over time for the study sample. LIMITATIONS: A limitation of the CaPSURE data is that DM is only self-reported by the participants at baseline, and thus the length of diagnosis and additional co-morbidity is unknown and can introduce bias in the study.
Eller et al., (2006) USA 20/22 90% – B3	Compare HRQoL for men receiving intensity modulated radiotherapy with RP.	PARTICIPANTS: N=159. DEMOGRAPHICS: **Age** RP 58.8 years (SD7.1), IMRT+HDR 68.4 years (SD 7.3), IMRT +BT 67.2 years (SD6.9), (P<0.001), **Race** RP white 85.7%, IMRT + HDR white 89.8%, IMRT + BT white 82% (P=0.486) **Employment** RP employed 79.8%, IMRT + HDR employed 38.8 %, IMRT + BT 49.2% (P<0.001). **Education** College and above RP 81.6%, IMRT + HDR 69.4%, IMRT + BT 60.6% (P=0.027). CLINICAL: T1 to T2 disease, N=49 RP, IMRT + HDR N=49, IMRT + BT N=61	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1 and 3 months. MEASURES: Demographic and clinical, Prostate Symptom Self-Report (PSSR), Symptom checklist (SCL-90) Anxiety Subscale, Epidemiological Studies for Depression Scale, Ways of Coping, SUPPH, FACT-P. ATTRITION: N=159, the analysis was based on N=124 who completed data at all time points. There were no significant differences between responders and non-responders.	Men in the RP group were more likely to be younger, higher education and working **Predictors of HRQoL**: **Physical well-being**: bowel symptoms, Sexual dysfunction, Depression, coping. **Social well-being**,: sexual symptoms, Depression, positive coping. **Emotional well-being**: urinary symptoms, sexual symptoms, depression. **Functional well-being**: bowel symptoms, sexual symptoms, depression, perceived stress, positive attitude. Treatment type did not contribute to any of the regression models. Thus physical and psychosocial factors significantly predictor HRQoL in men with PC. Depressive symptoms and urinary symptoms were highest in the IMRT + BT after treatment. LIMITATIONS: Selection bias is possible. The follow-up period is short and limited to acute phase after treatment.
Miller et al., (2005) USA 18/22, 81% – B3	Assess HRQoL in men with PC 4 and 8 years after treatment	PARTICIPANTS: N=964, N=709 consented (73.5%). There were not differences between responders and non-responders. DEMOGRAPHICS: **Age median** control 69.1 years, RP 67.2 years, RT 75.7 years, BT 70.4 years. **Marital** married control 79.4%, RP 875, RT 89.7%, BT 93.4%, **Race** white control 97%, RP 96.6%, RT 94.4%, BT 88.7%. **Education** high school control 100%, RP 94.3%, RT 95.4%, BT 91.8%. CLINICAL: T1-T3 disease, RP N=665 , RT N=147, BT, 84, Controls N=112 Median years since primary therapy RP 6.5 years, RT 6.3 years, BT 5.4 years.	DESIGN: Prospective longitudinal. TIME POINTS: 4 and 8 years after treatment. MEASURES: Demographic and clinical data, SF-12, EPIC. ATTRITION: Attrition and missing data not reported.	RP group reported most problems with urinary and sexual function. BT participants reported significantly worse urinary irritation-obstructive, urinary incontinence, bowel and sexual function. All groups has similar general HRQoL (SF-12) for the treatment groups. No significant change in SF-12 at 4 and 8 years in either group. Significant improvements were reported for urinary irritative/obstructive in the BT group, over time. RP group urinary, bowel and sexual function were similar at follow-up Predictors at 8 years: age was associated with urinary incontinence LIMITATIONS: No pre-treatment HRQoL evaluation undertaken thus the study was not able to control for baseline HRQoL between groups. Recruitment and non-responder bias may influence the results.
Wu et al., (2008)	To evaluate HRQoL for	PARTICIPANTS: N=2204	DESIGN: Prospective longitudinal.	Hormone therapy adjuvant to RP, BT, or RT there was a temporary worsening of sexual functioning that began to improve at 9

USA 22/24 91% – B3	men treated with multimodal therapy for men with PC.	DEMOGRAPHICS: The majority of men were approx <60 years, white ethnicity, and well educated. CLINICAL: RP N=1427, RT N=267, BT N=510. All patients would receive multimodal treatment for PC. RP alone N=1290, RP and ADT N=121, RP + RT N=16, RT alone N=83, RT and ADT N=184, BT alone N=246, BT + RT N=144, BT + RT + ADT N=59. The average length of ADT was 5 years mean (SD 3.7 years).	TIME POINTS: Baseline (before treatment) to 2 years after treatment. MEASURES: Demographic and clinical data, Charleston Co-morbidity rating scale, RAND SF-36, UCLA-PCI ATTRITION: No missing data was reported.	months post treatment. When RT was given in conjunction with BT there was continuous worsening of urinary function at 2 years follow-up. Multimodal therapy can cause declines in HRQoL in urinary, sexual and bowel domains for men with PC. LIMITATIONS: The analysis of RP + RT is very small and makes generalisabilty of the findings difficult. Possible bias between the responders and non-responders as part of the larger CaPSURE database.
Sullivan et al., (2007) USA 21/24 87% – B3	Assess HRQoL for men with HRPC.	PARTICIPANTS: N=280. DEMOGRAPHICS: **Age** mean age was 72 years, **Race** white 98%. CLINICAL: HRPC, mean PSA was 235, 345, 410, 421, baseline, 3, 6, 9 months respectively.	DESIGN: Prospective longitudinal TIME POINTS: At consent, 3, 6, 9 months follow-up. MEASURES: Demographic and clinical data, EORTC-C30, FACT-P, EQ-5D. PARTICIPANTS: Non-responses varied FACT-P and EORTC 89-95%; EQ-5D 90-04%. Missing data at 9 months was higher than at baseline. ATTRITION: From consent to the 9 months follow-up, the sample size decreased by 44% to N=157. N=83 deaths	30% died within the 9 months follow-up reflected the rapid progression of reduced HRQoL over the 9 months follow-up. The domains of HRQoL that did not reach significance were cognitive functioning, insomnia, diarrhoea, and financial difficulties. 40% of sample reported worse pain overtime. LIMITATIONS: There were numerous treatments for HRPC and these were not taken into consideration in the analysis, which could have influenced the results. There is also the potential for recruitment bias.
Rogers et al., (2006). USA 17/20 85% – B3	Assess HRQoL in men receiving LRP	PARTICIPANTS: N= 424 DEMOGRAPHICS: **Age** mean 57.9 (SD not reported). No further demographics reported. CLINICAL: Stage T1 to T2. Bilateral nerve sparing was performed on 65.7%, and unilateral 26.2% of the participants receiving LRP. .	DESIGN: Prospective longitudinal TIME POINTS: Before surgery, 3, 6, 12 months after surgery. MEASURES: Age and clinical, SF-12, EPIC. (Group 1 <50years, Group 2 50-59 years, Group 3 >60 years) ATTRITION: N=424 over all response rate was 89%. Differences between responders and non-responders were not reported.	88% of the men reported using 1 pad or less daily at one year. Younger men were more likely to achieve using only 1 pad or less at 12 months P<0.01). 60.5% bilateral nerve sparing LRP were engaging in intercourse at 12 months without phosphodiesterase-5-inhibitors P=0.01. Nerve sparing LRP was not predictive of men returning to baseline urinary function, but was the only predictor of return to baseline sexual function. No men older than 50 years experienced significant urinary incontinence. LIMITATIONS: There was control for co-morbid conditions. In addition, recruitment bias and attrition bias are possible and limits the generalisabilty of findings.
Montgomery et al., (2006). USA 20/22 90% – B3	Examine the effects of obesity on men treated with RP.	PARTICIPANTS: 575 men undergoing RP was approached. N=472 consented 82% response rate. DEMOGRAPHICS: **Age** 59.2 years (mean, SD not reported). **Race** the number of black men was small N=13, however a large proportion was obese or severely obese compared to white men (black 53.8% vs. white 26.5%, P=0.008). **Married**	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before surgery), 1, 4, 12, 24, 36 months after surgery. MEASURES: Demographic and clinical, EPIC and SF-12.	At 36 months the rate of PC recurrence for obese and severely obese was significant. Obese and severely obese participants also needed adjuvant HT at high rate than normal BMI men. No significant difference in clinical stages, Gleason scores, positive surgical margins between the groups divided by BMI. Higher BMI group had worse scores on hormonal/vitality function. no differences between urinary, bowel and sexual function in HRQoL

		the large majority of men were married 90+%. **Education** approx 80% were college and higher. CLINICAL: BMI distribution 22.1% normal BMI, 51.6% overweight, 19.7% obese, 6.6% severely obese. All men T1 to T2 disease. **Co-morbidities** the majority of men has 0-1 85%.	ATTRITION: N=472, N=376 completed at least one questionnaire.	in BMI groups. LIMITATIONS: Nerve-sparing procedures were not reported as this may have influenced outcomes. It is possible for attrition bias., the influence of additional co-morbidity was not explored.
Kubler et al., (2006) USA 18/22 81% – B3	Assess the impact of nerve-sparing techniques for RP and HRQoL	PARTICIPANTS: N=265 DEMOGRAPHICS: **Age** median 60.6 years. Me undergoing nerve-sparing were younger 59.2 years, non-nerve sparing 62.1 years (P=0.002). No other demographics reported. CLINICAL: N=153 non nerve sparing, N=112 nerve sparing. All T1 to T3 disease stage	DESIGN: Prospective longitudinal. TIME POINTS: Preoperative, 3, 6, after surgery. MEASURES: Age and clinical data, EPIC. PARTICIPANTS: for the N=265 attrition or missing data is not reported.	Participants reported an erection firm enough for intercourse at 23.8 months in the nerve-sparing groups, in contrast to the non-nerve sparing groups. Median time to continence (not wearing a pad) was 4.8 months in the nerve-sparing group, and 6.1 in the non-nerve sparing group (P<0.0001). Predictor variables: using multivariate logistical regression **Erectile function**: nerve sparing techniques, better pre-operative sexual function**. Urine function**: nerve sparing technique, age. In sum, nerve-sparing techniques may increase the chances of higher levels of potency and improved urinary function compared to non-nerve sparing techniques. LIMITATIONS: It is possible for recruitment and attrition bias, this was not addressed in this paper. There was also limited demographic data presented for this study sample and limits generalisabilty.
Namiki et al., (2006) Japan 21/22 95% – B3	Assessed HRQoL comparing IMRT and conformal RT (con RT).	PARTICIPANTS: N=140. DEMOGRAPHICS: **Age** con RT median 73.5 years (range 47-83), IMRT median 72 years (range 56-83). **Marital** married Con RT N=107, not married N=3, IMRT married N=28, not married N=1. CLINICAL: T1-T3 Con RT N=110, IMRT N=30, most frequent co-morbidity reported was hypertension in both groups.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (after diagnosis), 3, 6, 12, 18, 24. MEASURES: Demographic and clinical data, SF-36, UCLA-PCI. ATTRITION: No comparison was made between responders and non-responders.	The 2 groups were not significantly difference for age, Gleason, PSA, for tumour staging. HRQoL baseline no different in either group. Con RT group reported more problems with role limitations, emotional problems and physical problems compared to the IMRT. Urinary function problems were not significantly different at any of the time points in either group. Bowel function problems at 3 and 6 months more problematic for con RT compared to the IMRT. Sexual function was better at 18 months for the IMRT group than the con RT group. The impact of HT did not yield any significant impact on urinary, bowel of sexual function. In sum, the comparison of these treatments conveys a different trajectory for recovery for men receiving con RT and IMRT on HRQoL. LIMITATIONS: Caution is drawn to the statistical power to compare the treatment groups due to small N in the IMRT group. Possible for selection and attrition bias.

Kato et al., (2007) Japan 18/20 90% – B3	Assess HRQoL for men with PC receiving HT.	PARTICIPANTS: N=289, were asked to complete questionnaires pre-diagnosis (at prostate biopsies). N=123 has confirmed PC , N=56 received HT. DEMOGRAPHICS: **Age** mean 76.0 years (SD 6.7). No further demographics reported. CLINICAL: T1-T2 N=77, T3 N=17, T4-N1 N=18	DESIGN: Prospective longitudinal. TIME POINTS: pre-diagnosis, 3, 6, 12 months after treatment. MEASURES: Age, clinical, UCLA-PCI, SF-36 ATTRITION: N=56, 3 months 71.4%, 6 months 76.8 %, 12 months 66.1%, response	Change over time for HRQoL in men with localised disease SF-36 scales, only a decline in vitality at 6 and 12 months. Metastatic disease group improvements in pain at 3 and 12 months , vitality at 12 months, emotional-role and mental well-being at 6 months. Urinary function improved at 3 months, 6 months, and 12 months in metastatic group. All mens did not report any significant difference in score changes for bowel function or bother at any follow-up time points. As sexual function deteriorated over time at 3, 6 and 12 months. In summary, patient with metastatic disease on HT was found to have the greatest improvement in pain, vitality, mental well-being and role-emotional over time, compared to localized disease. LIMITATIONS: Study sample biased toward Japanese men, thus limits the generalisabilty of the results. Potential for recruitment bias, the impact of co-morbid conditions were not reported.
Namiki et al., (2005) Japan 20/22 90% – B3	Assess the impact of men receiving RP with or without HT for PC.	PARTICIPANTS: N=109 DEMOGRAPHICS: **Age** RP mean 66.8 years (SD 5.1, RP + HT mean 68.3 years (SD 5.1) (P=0.176).**Martial** married RP 94%, RP+ HT married 92%. **Employment** retired RP 47%, Retired RP + HT 54%. CLINICAL: RP N=72, RP + HT N=26	DESIGN: Prospective longitudinal. TIME POINTS: Before RP (but not before hormonal therapy), 3, 6, 12 months after RP. MEASURES: Demographic and clinical data, SF-36, UCLA-PCI. ATTRITION: 3 months 87%, 6 months 84%, 12 months 83%	RP group physical role limitations and emotional problems significantly worsened 3 months. Mental well-being improved over time compared to baseline. The RP + HT group reported significantly worse scores for role limitation due to physical problems, social functioning and mental health at baseline compared to RP group. Urinary function decreased at 3 months, and then started to recover at 6 and 12 months (P<0.05), however was still substantially lower than baseline. Bowel function was problematic in either group. Sexual function was not significantly different in the 2 groups, and reported substantial worsening scores at all follow-up times. LIMITATIONS: No control for baseline HRQoL before participants started their HT, this introduced bias in results. Potential for recruitment bias, ethnicity was not reported, as this may limit the generalisabilty of the results.
Pinkawa et al., (2007) USA 19/24 79% – B3	Assess the impact of prostate volume on HRQoL for participants treated with RT.	PARTICIPANTS: N=224 DEMOGRAPHICS: **Age** small prostate 71 (median, range 45-82), large prostate 72 (median, range 55-85). No further demographics reported. CLINICAL: 3 most frequent co-morbidities coronary heart disease 50%, hypertension 47%, diabetes 26%, T stage <2	DESIGN: Prospective longitudinal TIME POINTS: Baselines (before RT), on the last day of RT, 2 month (median, range 6 weeks - 6 months) and 16 months (median, range 12-20 months) MEASURES: Age no further demographics were reported. Clinical and the Expanded Prostate Cancer	Adjuvant HT participants reported significantly worse urinary function and urinary incontinence scores at all follow up time points (P=<0.01). Significantly worse bowel function scores were found before and after 1 year after radiotherapy (median 92 with HT vs. 96 without HT) at baseline and median of 16 months. **Significant predictors** of a worse urinary function were a large size of prostate volume, small bladder volume and use of HT.

		small prostate 71%, large prostate 87%, HT small prostate 41%, large prostate 19% (P=0.01).	Index, ATTRITION: N=224, N=204 baseline, N=131 on the last day of RT, N=180 at 2 months (median), N=204 at 16 months (median).	LIMITATIONS: No demographic data was presented, known predictors of disease-specific HRQoL. There is the possibility of selection bias.
Soderdahl et al., (2005) USA 19/22 86% – B3	Compare HRQoL of men treated with RP, LRP and BT.	PARTICIPANTS: N =453 DEMOGRAPHICS: **Age** RP median 59, LRP median 61, BT median 68 (P<0.001), **Race** white RP 70.9 %, LRP 75.3, BT 77.5%. CLINICAL: N=117 LRP, N=186 RP, N=150 BT. All groups reported 1 as the number of co-morbidities.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1, 3, 6, 9, 12 months after treatment. MEASURES: Demographic and clinical, SF-36, UCLA PCI, American Urological Association Symptom Index. ATTRITION: N=453, attrition was not reported. In the discussion, it was reported that the RP groups data completion was below 50%, thus responder bias is possible.	SF-36 general domains across all treatment groups reported an initial decline, which returned to baseline at 12 months. Prostate cancer-specific HRQoL affected the difference treatment in different ways. The RP and LRP reported the worse sexual function and the worse urinary function in the 12 months follow-up. Reduced bowel function was initial worse for the BT group, however at 12 months all the treatment modality groups reported similar scores. BT group reported worse urinary function at 1 month, 3 months, and 6 months, however at 12 months the means scores were very similar. Sexual function at 1 month across all treatments groups was significantly worse and at 12 months scores did not reach baseline function. Nerve-sparing surgery did not affect sexual function at any of the follow-up time points. RP, LRP and BT has little impact on general HRQoL, but significant impacts on disease-specific HRQoL over time. LIMITATIONS: Potential for responder and non-responder bias. The LRP had an excellent response rate, which the authors report the surgeons had a proactive approach to take part in the study.
Lips et al., (2008) Netherlands 21/22 95% – B3	Assess HRQoL after high dose intensity modulated radiotherapy (IMRT) using gold fiducial markers position verification.	PARTICIPANTS: N=116. DEMOGRAPHICS: **Age** 68 years (mean, range 46-79). No further demographic data reported. CLINICAL: Locally advanced cancer. HT no treatment 62%, short-term less than 6 months 27%, long-term <36 months 11%.	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before treatment), 1, 6, 36 months after treatment. MEASURES: Age and clinical data. SF-26, EORTC C30 + PR25. ATTRITION: N=116, N=15 lost to follow-up, N=6 died. The overall response rate was reported high, except for sexual activity. The analysis is based on N=95.	Within the 3 years N=2 developed GI toxicity radiation proctitis. This paper used a 10> score difference as a clinically meaning fully difference. No significant differences in the general HRQoL domains. Sexual function/activity showed a clinically relevant decrease of 12 points after 3 years, initially worse at 1 month and persisted at 6 months and 3 years. Mental health and emotional role scores consistently improved over all the follow-up time points and exceeded baseline values. Participants treated with HT had worse baseline sexual function, but similar reports to sexual function for participants who did not receive treatment. HRQoL returned to baseline and had no significant or clinically meaningful differences apart from sexual function at 3 years. LIMITATIONS: There is the potential for selection bias.
Hashine et al., (2009) Japan 20/22 91% –	Assess HRQoL for men treated with RP and	PARTICIPANTS: N=96 treated for RP and N=88 for BT. The total number of participants approached and decline were N=8.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1, 3, 6, 12 months follow-up after treatment.	HRQoL scores were worse at baseline for the RP compared to the BT. 1 month HRQoL scores were significantly worse than baseline for physical functioning, role physical, bodily pain, vitality and social functioning for RP with recovery at 3 months except for

B 3	BT for PC.	DEMOGRAPHICS: No demographic data CLINICAL: RP N=96, BT N=88. Nerve-sparing surgery was performed in N=12 participants, N=6 had RT after BT.	MEASURES: Demographic and clinical data. SF-8 (Japanese version, validity and reliability not reported). EPIC. ATTRITION: Response rates were 82.1% in the RP and 89.1% in the BT	bodily pain, which recovered at 6 months. Physical functioning, role physical, vitality and social functioning exceed baseline reported scores at 6 and 12 months in RP. BT group, role physical and social functioning at 1 month was worse that the baseline score and recovered 3 months, mental health component improved over baseline scores at 12 months. At 3 months HRQoL were worse in the RP, but there were no significant difference in either group at 6 months. Urinary incontinence in the BT was recovered by three month, but remained worse than RP group until 12 months follow-up. Urinary irritative/obstruction was worse than baseline at 1 month in both groups, RP recovered and improved baseline score at 3 months. BT group reported deteriorating urinary irritative/obstructive at 6 months. Bowel function was worse in the BT group at 3 and 6 months compared to RP. Nerve sparing surgery gradually improved sexual function over time compared to non-nerve sparing techniques. BT group had better overall HRQoL except for urinary irritative and bowel function, however these resolved overtime. LIMITATIONS: Study sample biased in favour of Japanese men. There is the potential for selection bias and attrition bias.
Hoffman et al., (2006) USA 21/22 95% - B3	Assess HRQoL for men with PC.	PARTICIPANTS: Total N=11 137 (CAP Sure database), N=5672 were suitable. N=3533 (62% completed questionnaires) at 6 and 12 months. The current analysis used data collected from men aged 75 to 84 years at diagnosis. RP and RT N=175, HT or AC/WW N=290. DEMOGRAPHICS: **Age** 75-79 years N=327 (70.25), 80-84 years N=138 (29.8%). **Race** White N=364 (84.2%), **Marital** married N=343 (72.6%), **Education** college and higher 68.6%. CLINICAL: All participants had localized prostate cancer. Some men had reported co-morbidities. Most men at baseline had no urine or bowel problems. 29% reported having moderate to big sexual problems. N=39 RP, N=137 RT, N=290 were manage conservatively on HT and N=174 no treatment.	DESIGN: Prospective longitudinal. TIME POINTS: baseline and 12 and 24 months after diagnosis MEASURES: Demographic and clinical data, SF-36, Charleston Index, Disease-specific, (the name of the measure is not reports). ATTRITION: No attrition reported at used data from an observational database, so not having missing data at baseline was one of the criteria for inclusion. At 24 months follow-up overall 74% completed the questionnaire. There was a difference between responders and non-responders, responders were more likely to be white, educated and married, the results not reported.	Men receiving aggressive treatment (RP RT) has overall worse urinary function, than the conservative group (HT AS). Men in the aggressive group were more likely to worse HRQOL 24 months after diagnosis. Men who received aggressive treatment had significantly higher general health (66.8 vs. 59.2, P=0.04) but more physical problems (60.8 vs. 47.7, P=0.04) than men being conservatively managed. LIMITATIONS: Attrition bias was reported as a possibility in this study.

Howlett et al., (2010) USA 22/22 100% – B3	Assess HRQoL for men undergoing RT	PARTICIPANTS: N=180, N=82 (43.6%) consented. No differences in demographics between the responders and non-responders. DEMOGRAPHICS: **Age** mean 67.1 years (SD not reported), **Race** white 79%, **Education** well educated mean 16.3 years. CLINICAL: Most men had T1 stage disease 51%, 53% received neoadjuvant HT before RT, 76% underwent whole pelvis with conformal boast.	DESIGN: Prospective longitudinal. TIME POINTS: Before treatment and at the end of RT. MEASURES: Demographic and clinical data, Karnofsky Performance Status, Centre of Epidemiological Studies-Depression Scale, Spielberg State Anxiety Scale, QoL Scale Patient Version, and single item question "is your sexuality impacted by your illness?" ATTRITION: Limited attrition data reported. Only 70 men completed the sexual function question.	Baseline 50% reported a problem with sexual function. Men with no urinary, bowel and sexual dysfunction reported significantly less anxiety and depression and higher HRQoL atT1 and T2 LIMITATIONS: Large proportion of participants were white, educated and married, thus has the potential to limit the generalizability of the results.
Hashine et al., 2008 Japan 19/22 86% - B3	Assess HRQoL for men treated with RP and BT.	PARTICIPANTS: N=122 treated with RP and N=82 treated with BT. To number of men approached was not reported. DEMOGRAPHICS: **Age** median in the RP 68 years, BT 70.5 years, CLINICAL: Neoadjuvant HT was used in N=18 of the men in the BT and N=8 in the RP. Nerve-sparing was performed in N=22 participants.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1, 3, 6, 12 months after treatment. MEASURES: Age and clinical data, SF-36, UCLA-PCI, ATTRITION: The response rates were RP 70.8% and BT 76.2%.	RP group all of the HRQoL components (except for general health and mental health) were significantly worse at 1 month after surgery but recovered at 3 months. However, role physical and bodily pain was worse at 3 months compared to baseline. HRQoL scores were better for men in the BT compared to the RP. At 1 months BT participants reported significantly worse urinary bother than the RP group that lost significance at subsequent follow-up. HRQoL recovered at 3 months in the RP group. LIMITATIONS: There is the possibility for section bias. No measure of co-morbidity that may have confounded the results.
Namiki et al., (2009) Japan 20/22 90% – B3	Assess HRQoL for men with Pc older than 70 years old	PARTICIPANTS: N=750, N=319 consented DEMOGRAPHICS: **Age** 73.5 (mean, SD 2.8) years. No further demographics reported. CLINICAL: Men treated by RP and RT. Most of the RT participants received HT. 43% did not undergo nerve-sparing procedures. Co-morbidities were reported.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 3, 6, 12, 18, 24 months after treatment. MEASURES: Age and clinical data, SF-36, UCLA-PCI. ATTRITION: N=319, N=4 died, N=8 excluded because of disease recurrence, only participants with baseline and one of the last 2 follow-up time points were included, N=284 (N=166 RP and N=118 RT) Response rates at time points above starting with baseline; 100%, 95%, 97%, 91%, 87%, 92%.	RP had better scores for baseline physical function, role limitation due to physical and role emotional problems compared to RT group. RP reported better sexual function compared to the RT at baseline. No difference in urine and bowel function in either group. RP had a worse urine function at 3months, but improved over the 6, 12, 18 and 24 months, but at 24 months function was still statistically lower than baseline. Nerve-sparing group reported significantly better sexual function compared to the participants who did not received nerve sparing surgery. Predictors at 24 months HRQoL: RT was associated with better urinary function and less sexual bother compared to RP. LIMITATIONS: Potential for selection bias, also the use of sexual aids and urinary function aids were not reported this may influence the results.
Namiki et al., (2009) Japan	Assess HRQoL for men	PARTICIPANTS: N=97 treated for 3D conformal RT and N=36 from IMRT (N=133 total participants in study).	DESIGN: Prospective longitudinal TIME POINTS: Baseline (after diagnosis), 3, 6, 12, 18, 24,	The SF-36 no significant differences between the groups or at any of the follow-up time points. UCLA-PCI no difference in either group for urinary function and bother at any time point. Bowel

19/22 86% – B3	comparing IMRT and 3D conformal RT	DEMOGRAPHICS: **Age** IMRT 71 (SD 6) years, 3D RT 73 (SD 4) years P=0.05, **Marital** married IMRT 94%, 3DRT 94% P=0.50. **Employment** Retired IMRT 75%, 3DRT 63%. CLINICAL: **Co-morbidities** IMRT none 28%, 3DRT 21%.	60 months after diagnosis. MEASURES: Demographic and clinical data, SF-36, UCLA-PCI ATTRITION: N=133, N=115, N=109, N=110, N=108, N=114 at baseline, 3, 6, 12, 18, 24, 60 months respectively. The differences between responders and non-responders were not reported.	function had no significant differences at baseline for the 2 groups. 60 months after treatment, the 3DRT group had significantly bowel function and bother scores compared to the IMRT group. 3DRT group were more likely to reported rectal urgency, diarrhoea, cramp pain than those in the IMRT group. Sexual function was worse in the 3DRT group, significant decline at 3 months and remained significantly lower than at baseline. 3DRT group showed no significant difference at 2 years (either improvement or worsening). There were no significant changes in the IMRT group for sexual function and bother for the follow-up time points. LIMITATIONS: There was small N=in the IMRT group. This study did not include the use of sexual aids which may have been a possible bias. Selection bias and attrition bias is possible.
Namiki et al., (2009) Japan 20/22 90% – B3	Assess HRQoL over 5 years for men treated with RP for PC.	PARTICIPANTS: N=154 DEMOGRAPHICS: Of the N=143 **Age** 65.8 (SD 5.6) years, **Marital** 94%, **Employment** Retired 48%. CLINICAL: All T1-T3, nerve sparing 61%, Salvage therapy none 83%, co-morbidity none 31%, 1-2 63%.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before RP), 3, 6, 12, 18, 24, 36, 48, 60 months after RP. MEASURES: Demographic and clinical data, SF-36 and UCLA-PCI. ATTRITION: The questionnaire response rates were 95%, 97%, 100%, 91%, 99%, 100%, 91%, 87%, at 3, 6, 12, 18, 24, 36, 48, 60 months respectively. Testing for attrition bias was not reported.	SF-36 role limitations due to physical problems and bodily pain significantly decreased at 3 months. Social functioning scores were statistically higher at 2 years than at baseline. Mental health scores significantly improved at all-time points compared to baseline. Urinary control significantly declined at 3 months and urinary control was still significantly lower than baseline function at all-time points. Nerve-sparing techniques did not have any relationship with recovery of urinary function. No significant differences were observed for bowel function or bowels bother. Sexual function was statistically worse at all time points. 60 months 34% had regained baseline sexual function scores. LIMITATIONS: Selection bias may have been possible, the use of sexual aids was not reported which introduces bias.
Namiki et al., (2009) Japan 20/22 90%, – B3	Assess HRQoL for men >70 years old	PARTICIPANTS: N=205 DEMOGRAPHICS: **Age** 72.5 (SD1.9) years, **Marital** N=177 married, N=18 no other significant partner (not in relationship). **Employment** retired N=135, N=60 working. CLINICAL: Stage T1-T3 all RP, Co-morbidities 1> N=161, Salvage therapy N=167 none. Nerve-sparing techniques none N=78	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before RP), 3, 6, 12, 18, 25 months after RP. MEASURES: demographic and clinical data, SF-36 and UCLA-PCI ATTRITION: Response rates were 100%, 90%, 91%, 95%, 83%, 85%, at baseline, 3, 6, 12, 18, 24 months respectively.	Role limitations due to physical problems decreased at 3months and recovered at 6 months. Mental health scores at 12 months were statistically higher than at baseline score. Urinary function significantly worsened at 3 months and remained statistically lower at 25 months compared to baseline. There were no significant differences in bowel function at any of the follow-up time points. Sexual function scores declines over the 24 months. LIMITATIONS: It is possible for selection bias and attrition bias. The used of sexual aids was not reported as this may have influenced the findings. Study sample bias in favour of Japanese

				men.
Namiki et al., (2008) USA 18/20 90% H – B3	Compare HRQoL for men treated with RP or RT in Japan and USA	PARTICIPANTS: N=477 Japanese men, N=385 American men consented. DEMOGRAPHICS: **Age** Japan 67.2 (SD 5.5) years, American 60.1 (SD 7.2) years (P=0.008). **Race** Japan Asian 100%, American, White 85% CLINICAL: All T1-T3. Japan N=153 RT, RP N=324. America N=78 RT, RP N=307.Nerve-sparing Japan 69%, American 91%.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1, 2, 3, 4, 6, 8, 12, 18 , 24 months after treatment. MEASURES: Demographics and clinical data. UCLA-PCI and the American Urological Association Symptom Index (AUASI). ATTRITION: No attrition was reported.	PR group had better urinary function at baseline than RT group. Increasing age and co-morbidity predicted worse urinary function. 1 month after RP American men reported worse urinary function than Japanese men. Both groups regained urinary control over time and reported less distress. Trend of recovery of symptoms differed significantly by county. LIMITATIONS: Selection bias is possible and attrition bias possible. Potential bias secondary to cultural differences in interpretation of the questionnaire items. Additional demographics such as marital status employment, education demographic variables may have also influenced the findings.
Gore et al, (2009). USA 20/20 100% – B3	Assess HRQoL for localizes prostate cancer	PARTICIPANTS: N=475 DEMOGRAPHICS: **Age** RP 60.1 (SD 7.1) years, RT 70.8 (SD 7.3) years BT 68.4 (SD6.9) years (P<0.001). **Marital** Married/partner RP 83.4%, RT 82.0 %, BT 80% (P=0.75). **Education** College and more RP 73.6%, RT 71.8%, BT 59.6% (P=0.04) CLINICAL: RP N=307, RT N=78, BT N=90. All T1 to T3. Co-morbidity counts none RP 38.1%, RT 28.2%, BT 34.4 % (P=0.60) .	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before treatment), 1, 2, 4, 8, 12, 18, 24, 36, 42, 48. MEASURES: Demographic and clinical data. SF-38, UCLA-PCI and AUASI. ATTRITION: Participants who completed the 48 month survey were older 63.7 (SD 8.1), than those who did not complete it 60.2 (SD 7.1) P=0.001.	Physical and mental well-being were largely unaffected by the treatments for localized prostate cancer. Urinary function was worse for the RP. Incontinences was more prevalent in RP than the BT group. Sexual function was negatively affected in all treatment groups. RT group experienced a gradual decline in sexual function over 28 months. However, the BT participants experienced a gradual improvement over time. RT and BT reported more bowel dysfunction than the RP participants. LIMITATIONS: Participants in the RP had better baseline function of HRQoL compared to the other groups and may have cause a bias in the results. Selection bias is possible. The used of hormone therapy was not evaluated on HRQoL as this may have influenced the reported results.
Pinkawa et al., (2009) Germany 21/24 87% - B3	Compare HRQoL for participants treated with BT and RT for PC.	PARTICIPANTS: BT N=52, RT N=52. DEMOGRAPHICS: **Age** BT 68 mean (range 51-72) years, RT 68 mean (range 48-77) years. No further demographics reported. CLINICAL: T1 to T2 staging. Co-morbidities BT 52%, RT 48%. Most common co-morbidity Hypertension BT 21%, RT 21%.	DESIGN: Prospective longitudinal. TIME POINTS: Before BT or RT, at the last day of RT or 1 months after BT, and f6 months after treatment. MEASURES: Age and clinical data, EPIC ATTRITION: Response rate 98%, at baseline and 65% for all other questionnaires.	Obstructive/irritative symptoms were reported higher in the BT compared to the RT at baselines and at 16 months. Sexual function statistically worsened in both groups with no significant difference between the groups. Bowel function problems were more frequently reported in the RT group. BT participants are more likely to experience urinary irritative symptoms and less proctitis. RT participants are more like to experience proctitis than urinary irritative symptoms. LIMITATIONS: General HRQoL was not measured. No additional demographic data was reported known predictors of HRQoL. Selection bias and attrition bias' is possible.

Namiki et al., (2006) Japan 21/22 95% – B3	Assess HRQoL for men treated with BT and RP for PC.	PARTICIPANTS: N=70 BT and N=67 RP (total N=137). DEMOGRAPHICS: **Age** RP 64.3 mean (SD6.5) years BT 67 mean (6.5) (P=0.024). No further demographics reported. CLINICAL: All T1 to T2. Nerve-sparing procedures performed in N=56 RP participants.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1, 3, 6, and 12 months after treatment. MEASURES: Age and clinical data. SF-36 and the UCLA-PCI, IPSS ATTRITION: N=137, N=117, N=130, N=119 and N=115 returned questionnaires at baseline, 1, 3, 6, and 12 months. .	RP group significantly worse role limitation due to physical problems, emotional problems, social functioning, bodily pain and mental health and vitality at 3 months and improved at 6 months. BT reported no significant worsening in general HRQoL during any of the follow-up. Urinary function worsened for RP group but a gradual trend of improvement was seen overtime, but remained statistically worse at all-time points. Sexual function in the RP group improved for participants who were treated with nerve-sparing surgery compared to men who did not receive nerve-sparing surgery. RP group had significantly worse sexual function than the BT group at all-time points. BT participants reported a doubled IPSS score at 3 months post treatment but recovered by 12 months. LIMITATIONS: Possibility of selection and attrition bias.
Arredondo et al., (2007) USA 22/24 91% – B3	Assess HRQoL for men with biochemical relapse	PARTICIPANTS: N=897 analysis for RP alone, N=175 subset for secondary analysis. DEMOGRAPHICS: **Age** RP only <60 years 36.6%, 60-70 years 55.4%, >70 years 8.1%, RP + secondary treatment <60 30.7%, 60-70 years 56.8%, >70 years 12.5 (P=0.10). **Race** white RP only 87.2%, RP + treatment 90.3%. **Education** college and above RP only 65.7%, RP+ treatment 56.5% CLINICAL: Performed nerve-sparing surgery RP only 63.8%, RP + treatment 49.2% (P<0.001).	DESIGN: Prospective longitudinal TIME POINTS: compared data 27 months before the second treatment for biochemical relapse up to 39 months after second treatment. MEASURES: Demographic and clinical, SF-36, UCLA-PCI ATTRITION: Participants in this study had to, at minimum complete 1 questionnaire before and 1 questionnaire after their second treatment. The participants that were excluded for not returning the questionnaires were not statistically difference from those included.	Across all HRQoL RP + treatment reported worse scores than RP alone, these differences were still maintained after adjusting for baseline clinical and demographic characteristics. HRQoL is affected at 15 months before initiation of the second treatment. HRQoL show differences in all domains over time, with role-physical and sexual functioning being the largest clinically significant decline. HRQoL is not only affected by second treatment but start to decline approximately 15 months before treatment begins. LIMITATIONS: Selection bias is possible. Results are limited to RP patient only thus limited the generalisabilty of the findings.
Peters et al., (2008) USA 19/22 86% – B3	Assess the impact of single nucleotide polymorphisms as a predictor of HRQoL.	PARTICIPANTS: N=141 DEMOGRAPHICS: **Age** 66 years (range 46-79), **Race** White 77%, no further demographics reported. CLINICAL: All participants treated with RT.	DESIGN: Prospective longitudinal TIME POINTS: Before treatment and at 6 monthly intervals (median follow-up 51.3 months, range 12 to 138 months) MEASURES: Demographic and clinical data. IPSS, International Index Erectile Function. Lymphocyte and DNA extraction data. ATTRITION: Attrition data not reported.	An association of certain TGFBI genotypes and the development of both erectile dysfunction and late rectal bleeding. 3% reported (N=4 out of N=141) overall poor urinary function measured by the IPSS. No association found with genotypes and urinary disease-specific HRQoL. LIMITATIONS: Selection and attrition bias is possible. Reported that the study was underpowered.

Robinson et al., (2009). Canada 20/22 90% – B3	Compare HRQoL for RT and cryoablation	PARTICIPANTS: N-244 DEMOGRAPHICS: **Age** Cryoablation median 69.4 (range 52.8 to 81.4) years, RT 68.6 (range 53.2 to 78.6) years. No further demographics reported. CLINICAL: All patients were T1 to T3. N=122 Cryoablation, N=122 RT. All participants were taking HT.	DESIGN: Prospective longitudinal TIME POINTS: Before treatment, 1.5, 3, 6, 12, 18, 24, 36 months after treatment. MEASURES: Age and clinical data, EORTC-C30 UCLA-PCI ATTRITION: Attrition was reported 87% approximately.	3 months the cryoablation urinary function improved compared to RT group. No difference in bowel function for either group. Cryoablation group had worse sexual function scores than RT, no group recovered to baseline sexual function. RT group reported better sexual function and better urinary function at 3 month and had better long-term sexual functioning compared to cryoablation. LIMITATIONS: All participants were taking HT, therefore it is possible that this would have influenced their HRQoL outcomes. Attrition bias is possible, use of self-management techniques no identifies as this may influence HRQoL.
Miller et al., (2007) USA 19/22 86% – B3	Compare HRQoL for men for men with RP and LRP.	PARTICIPANTS: N=162. DEMOGRAPHICS: **Age** 60.8 mean (SD not reported) years. No further demographics reported. CLINICAL: N=42 (26%) underwent LRP, N=120 (74% underwent RP. All T1-T2. The was no statistical difference between the groups for age.	DESIGN: Prospective longitudinal TIME POINTS: Baseline (pre-operatively 1 week recall), 1, 2, 3, 4, 5, 6 weeks post-op. MEASURES: Age, clinical data, SF-12, ATTRITION: overall response for the questionnaire was 80%, the proportion of missing data was 60%.	LRP group significantly better physical HRQoL compared to the RP. The mental HRQoL scale was not related to the surgical procedure. Return to baseline was assess and it was estimated that for the LRP was weeks 5-6 and for the RP was 6-7. LRP group had higher physical HRQoL and faster recovery of HRQoL than men in the RP group. LRP reported a higher baseline mental health summary score than the RP, this may have been due to optimistic believes about the new surgical procedures. LIMITATIONS: Retrospective memory recall bias. Attrition bias is also possible. Lack of demographics and co-morbidities. Unequal numbers in the surgical groups.
Kershaw et al., (2008) USA 20/22 90% – B3	Assess stress and coping model on HRQoL	PARTICIPANTS: N=429 dyads approached N=263 68.7%) recruitment rate. DEMOGRAPHICS: **Race** white 86%, African –American 13%,**marriage length** 31.8 mean (SD14) year, **Education** 16.1 mean (3.7) years patients, 14.9 mean (SD2.8) spouses. CLINICAL: N=121 patients, newly diagnosed (67%), advanced (20%) biochemical relapse (13%). Average length since diagnosis was 8 months	DESIGN: Prospective longitudinal TIME POINTS: Baseline at recruitment, 4 months and 8 months after recruitment. MEASURES: Demographic and clinical data, SF-12, Brief COPE, Appraisal of Caregiving Scales, Becks Hopelessness Scale, Mishel Uncertainty in Illness Scale, Current Concerns, Lewis Cancer Self Efficacy Scale, Personal Resources Questionnaire, Lewis Mutuality and Interpersonal Sensitivity Scale, General Symptom Distress of the Omega Screening Questionnaire. ATTRITION: Attrition not reported.	Predictors of better mental HRQoL – Participants had a better mental QoL at the 8 months follow-up if they had more active coping β=+.19, lower avoidant coping at 8 months β=-.31, less hopelessness at 4 months β=-.32, fewer baseline symptoms β=-34. Predictors of physical HRQoL – Participants had a better physical QoL at 8 months if they had a negative appraisal of their illness at 4 months β=-.30, fewer baseline symptoms β=-.26 and were in diagnosed phase of their disease B=+.25. Participants with more social support β=+.33 used more active coping at 8 months. LIMITATIONS: The sample may not be representative of all prostate cancer participants. Attrition not reported thus possible bias.
Jayadevappa et al., (2007) USA	Assess the impact of ethnic	PARTICIPANTS: N=214 DEMOGRAPHICS: **Age** white group 69.87 mean (SD4.5) years	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before treatment) 3, 6, 12	African American (AA) low HRQoL at diagnosis. AA was a predictor of worse role physical, role emotional, bodily pain, urinary function and bother at 12 months.

21/22 94% – B3	variation as a predictor of HRQoL	African-American (AA) 71.25 mean (SD 4.1) years (p<0.05). **Education** white college and more 68.57%, AA 30.51% (P=0.001). **Marital** married white group 77.54%, AA group 57.63% (P=0.004). CLINICAL: Staging T1-T3, treated with RP or RT.	months after treatment. MEASURES: Demographic and clinical data, SF-36, UCLA-PCI, Client Satisfaction Questionnaire, Charlson Co-morbidity Index ATTRITION: N=195, N=184, N=182, completed 3, 6, 12 months questionnaires respectively.	LIMITATIONS: Selection bias and attrition bias is possible.
Ward-Smith and Mehl, (2007) USA 19/22 86% – B3	Assess HRQoL for men treated with RP.	PARTICIPANTS: N=92, N=56 consented (61%) DEMOGRAPHICS: **Age** mean 50.2 (range 43-65) years, **Race** 100% white, **Marital** married 82%, **Education** College and higher 75%. **Employment** working 57%. CLINICAL: All men received RP. Nerve-sparing surgery was not reported, no further clinical data reported.	DESIGN: Protective longitudinal. TIME POINTS: Before surgery, 1 and 6 months after. MEASURES: Demographic and FACT-P ATTRITION: 100% completed all follow-up data collection.	Social well-being worsened from baseline to 3 months and 6 months. LIMITATIONS: This sample was homogeneous, thus limits the generalizability of results. Selection bias is possible.
Vodermark et al., (2009). Germany 20/22 90% – B3	Assess HRQoL for men treated with BT.	PARTICIPANTS: N=74, N=72 consented (97.4% selection rate). DEMOGRAPHICS: **Age** 67mean (SD 6) years. No further demographics reported. CLINICAL: N=17 (23%) received neoadjuvant HT. All T1 to T2 Gleason <7 and PSA <10ng/mL.	DESIGN: Prospective longitudinal TIME POINTS: Pre-treatment, 1 month and 1 years after BT. MEASURES: Age and clinical data. EORTC-C30 and PR-25 ATTRITION: 87.8% and 89.2%, at 1 and 12 months after BT respectively.	All functional scales (C30) were significantly worse at 1 month compared to baseline but recovered by 12 months. The emotional function scale improved over pre-treatment reports. Global HRQoL was not affected at any of the follow-up time points, and was similar scores to age match controls of a German population. Constipation was significantly worse at 1 and 12 months. Urinary symptom increased at both 1 month and 12 months compared to baseline. Sexual function questions were only completed by a minority of participants (54%). Thus limited the analysis of this function. LIMITATIONS: The use of sexual aids was not reported, and limited demographics as this is known to be predictive of HRQoL.
Zavala et al., (2009) USA 23/24 95% – B3	Assess HRQoL for low-income men with PC.	PARTICIPANTS: N=447, N=357 consented (80% selection rate). N=65 with metastatic disease which were excluded yielding a final sample of N=291. DEMOGRAPHICS: **Age** 73% were >60 years, **Marital** 75% were in a committed relationship, **Race** 53% Hispanic, 23% white **Education** 85% had high school education and less. All men 200% below federal poverty CLINICAL: PC all treatment and stages, except metastatic disease.	DESIGN: Prospective longitudinal. TIME POINTS: At IMPACT enrolment, 6 and 15 months after enrolment. MEASURES: Demographic and clinical, UCLA-PCI, SF-36, Charleston Co-morbidity Index, ATTRITION: N=291, N=291, N=182, at enrolment, 6 months, 15 months respectively.	RP group had worse urinary, bowel and sexual function at 15 months follow-up compared to other treatments. Men not in a committed relationship had significantly lower physical and mental components of HRQoL, urinary and bowel bother. A higher co-morbidity, less education predicted worse physical components summary scores. LIMITATIONS: This sample homogeneous sample of low-income men with PC, thus limits the generalizability.

DePuy et al., (2006) USA 17/20 85%– B3	Assess HRQoL in men with skeletal related events (SRE) with metastatic PC.	PARTICIPANTS: N=643 participants consented. Among participants who survived 6 months after randomization N=471 (73%) were included in the analysis. DEMOGRAPHICS: **Age** 71.7 mean (SD 7.4). No further demographics reported. CLINICAL: Participants with no SRE at 6 months (N=355), participants with 1 SRE at 6 months (N=78), participants with 2 SRE at 6 months (N=38).	DESIGN: Prospective longitudinal TIME POINTS: Baseline, 3, 6, weeks and every 6 weeks up to 24 months. MEASURES: Age and clinical, FACT-G, Brief Pain Inventory ATTRITION: Attrition not reported.	2 or more SRE predicted significantly worse physical well-being and worse levels of pain. Higher number of SREs predicted worse survival than patient without SREs. Significant differences were found between pain, physical, emotional and functional subscales with participants experiencing single vs. multiple SREs. LIMITATIONS: Using a different cut off might have yielded difference results, rather than 6 months for estimating the development of SREs.
Namiki et al., (2007) Japan 20/20 100% – B3	Assess HRQoL for men treated with RP with biochemical relapse and without relapse.	PARTICIPANTS: N=249 underwent a 2 year follow-up, N=46 men showed biochemical relapse. . DEMOGRAPHICS: There were no significant differences in age, marital status or co-morbidities. CLINICAL: N=46 RP with biochemical relapse, N=203 with RP with relapse.	DESIGN: Prospective longitudinal TIME POINTS: Before RP and 24 months after RP. MEASURES: Demographic and clinical data, UCLA-PCI and SF-36 ATTRITION: There was no attrition in this study, completion was 100%.	SF-36, physical problems, emotional problems, bodily pain and mental health (P=0.03) for men with biochemical relapse. Men without biochemical relapse had better mental health and social functioning and men with biochemical relapse. No difference in prostate cancer-specific HRQoL in either group at baseline. Urinary function worsened in both groups at 2 years and statistical difference in either group. Sexual function worsened in both groups at 2 years. Nerve-sparing surgical techniques group had better sexual functioning than non-nerve sparing. Younger men predicted better sexual and urine function. LIMITATIONS: It is possible for selection bias and small N in the biochemical relapse group.
Lips et al., (2007) Netherlands 17/20 85% – B3	Compare conformal RT with IMRT in men	PARTICIPANTS: N=78 conformal RT (70Gy), N=92 IMRT (76Gy). DEMOGRAPHICS: **Age** conformal 67 mean (range 47-78) years, IMRT 67 mean (range 49-79) years. No further demographics reported. CLINICAL: All T1-T4, no significant differences were found in clinical characteristic between the groups. Conformal N=9, IMRT N=24 treated with HT.	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before treatment), 1 and 6 months. MEASURES: Age and clinical data, EORTC-C30 and PR25, SF-36 ATTRITION: Attrition not clear from the paper.	The IMRT group reported less deterioration in HRQoL for all scales than the conformal RT group. Adjuvant HT participants reported more treatment related symptoms. HRQoL change overtime all participants: **Baseline vs. 1 month: SF-36:** Physical role restriction -15.0 (P<0.0001), vitality – 3.7 (P<0.01, C30: Emotional functioning 7.6 (P<0.0001), fatigue 6.0 (P<0.0001), constipation 4.4 (P<0.002), Diarrhoea 6.8 (P=0.002) PR25: Bowel symptoms 5.1 (P<0.0001), treatment related symptoms 3.2 (P<0.0001), sexual activity -9.8 (P<0.0001). **Baseline vs. 6 months:**SF-36: Emotional role restriction 10.6 (P=0.002), Mental health 3.8 (P=0.0002) C30: Emotional functioning 8.5 (P<0.0001) PR25: Treatment related symptoms 3.5 (P<0.0001), sexual activity -13.9 (P<0.0001). IMRT can provide a higher dose of radiation without a further deterioration on HRQoL. LIMITATIONS: the use of sexual aids and demographics were not

				reported, which could be a possible bias of the study.
Lit win et al., (2006) USA 21/22 95% – B3	Compare HRQoL for treatment for localized PC.	PARTICIPANTS: N=307 RP, N=78 RT, N=90 BT were treated for localized PC. 81.9% selection rate. DEMOGRAPHICS: **Age** RP 60.1 mean (SD 7.2) years, RT 70.8 mean (SD 7.3), BT 68.4 mean (SD 6.9) years (P<0.001). **Race** white RP 85.3%, RT White 84.6 %, BT 78.9 (P=0.34), **Marital** partnered RP 83.4%, RT 82%, BT 80% (P=0.75), **Education** college and more RP 73.6%, RT 71.8%, BT 59.6% (P<0.05) CLINICAL: , N=307 RP, N=78 RT, N=90 BT, all T1-T3	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before treatment), 1, 2, 4, 8, 12, 18, 24 months after treatment. MEASURES: Demographic and clinical data, SF-36, UCLA-PCI, AUASI. ATTRITION: Attrition was well reported for each time point. 72% response rate at 24 months.	All treatment groups HRQoL was worse at 1 month post treatment. BT group reported moderate to severe urinary obstruction and irritation. No significant change was seen in the physical or mental domain. RP group has the worse urinary control and sexual functioning than the radiation nerve-sparing surgery predicted better sexual function. Obstructive and irritative urinary symptoms were common in BT group. Urinary control and sexual function were better after RT than BT Among potent men, recovery of sexual function was best after RT and was equivalent to nerve-sparing surgery or BT. Sexual bother was more common thank urinary or bowel bother after all 3 treatment groups. Bowel dysfunction was more common in RT and BT than RP. Different treatment for localized PC affects HRQoL differently. LIMITATIONS: This study did not account for men receiving HT, co-morbidities or the use of sexual aids. Selection and attrition bias is possible.
Monahan et al., (2007) USA 20/22 90% – B3	Assess predictors (depressive symptoms and treatment type) of HRQoL.	PARTICIPANTS: N=105 DEMOGRAPHICS: **Age** 64.3 mean (SD 8.1) years, **Race** white 88%, **Education** College and higher 57%, **Marital** married 95% CLINICAL: Stage T1 to T3, RP N=58 (55%), RT N=28 (27%), BT N=19 (18%), NS-RPN=34 (58%)	DESIGN: Prospective longitudinal TIME POINTS: within 4 weeks of initial treatment completion, 4, 7, 12 months after treatment. MEASURES: Demographic and clinical data, Prostate Cancer Quality of Life Instrument (PC-QoL), SF-36, CES-D (depression instrument). ATTRITION: Attrition not reported in this paper.	Treatment type and age did not predict depression scores. Age was significantly associated with treatment type. RP participants were the youngest and RT were the oldest. African American and other races (not white) where more likely to choose. Higher education predicted higher depressive symptoms. Poorer sexual function predicted depressive symptoms. BT and RT generally reported better urinary function that RP participants. Depressive symptoms predicted all three prostate cancer-specific HRQoL. Depressive symptoms had a significant relationship with generic aspects of general HRQoL. BT group reported worse pain at 12 months, role limitations due to emotional problems at 7 months and social functioning at 7 months, compared to RT participants. Depressive symptoms measures at 4 weeks post treatment significantly predicted subsequent 4, 7, 12 months global HRQoL after adjusting for treatment, age, education, race and marital status. Depressive symptom was a stronger predictor of HRQoL than treatment types. LIMITATIONS: Although this study found that depressive symptoms predicted HRQoL, however it is possible that low HRQoL causes depressive symptoms? Research is needed to disentangle this relationship. Depressive symptoms were

				measures at 4 week post treatment but a pre-treatment baseline would have enabled a clearer understanding of the relationship without the influence of treatment effects.
Moinpour et al., (2008) USA 22/22 100% – B3	Assess HRQoL for participants treated with RP, randomly assigned to HT or observation only.	PARTICIPANTS: N=425 DEMOGRAPHICS: **Age** RP only 66 mean (range 57-79) years, RP + HT 64 mean (ranges 45-78) years, **Race** white RP only N=71, RP + HT 74%. CLINICAL: RP only N=107, RP + HT N=110, no significant differences were reported between clinical variables.	DESIGN: Prospective longitudinal TIME POINTS: Baseline (at randomization), 6 weeks, and annually for 5 years. MEASURES: Demographic and clinical data SF-20 and SF-36, disease-specific HRQoL (with a developed measure for this study) ATTRITION: Attrition rates were 95%, 91%, 90%, 88%, 76%, 73%, 72%, 67%, at baseline, 6 weeks, 6 months, 1, 2, 3, 4, 5 years respectively. N=217 in analysis.	RP + HT experienced more bowel dysfunction than patient receiving RP only. Urinary frequency was reported as more of a problem in the RP + HT group over the entire follow-up. RP + HT group had normal HRQoL by 5 years (51%) compared with participants on the RP had (69%). RP + HT had significantly higher symptom distress with increasing time (P=0.02). LIMITATIONS: The disease-specific HRQoL measure did not reported psychometric properties.
Korfage et al., (2005) Netherlands 21/22 95% – B3	Assess the impact on mental and HRQoL for men newly diagnosed with PC.	PARTICIPANTS: N=4193, N=3800 (88% response rate) of which N=52 men were diagnosed with PC which this paper is reporting on. DEMOGRAPHICS: **Age** 67.3 mean (SD 4.4) years. No further demographics reported. CLINICAL: RP N=18, RT N=1, BT N=13, WW N=1, Undecided N=1.	DESIGN: Prospective longitudinal. TIME POINTS: 2 Months before diagnosis, 1, 7 months after diagnosis. MEASURES: Age and clinical data, SF-36, EQ-5D ATTRITION: N=1 refused the second data collection.	Mental health significantly decreased from pre-diagnosed reports to 1 month after diagnosis. A PC diagnosis from a PSA screening can have a negative impact on men's mental health and self-rating of their health status. Thus evaluating men's health post-diagnosis/pre-treatment may lead to an underestimation of their mental health. LIMITATIONS: Different treatment would have influenced HRQoL at 7 months.
Kobuke et al., (2009) Japan 18/20 90% – B3	Assess HRQoL for men treated with RP and BT.	PARTICIPANTS: N=73 DEMOGRAPHICS: **Age** RP 67 median (range 54-75), BT 67 median (range 53-76) No further demographics reported. CLINICAL: N=37 RP, N=36 BT, Stage T1-T2, Nerve-sparing N=13, neoadjuvant HT RP N=13, BT N=0 Recurrences at 12 months RP N=3, BT N=0	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before treatment), 1, 3, 6, 12 months after treatment. MEASURES: Age and clinical data, SF-36, UCLA-PCI, IPSS ATTRITION: The average response rate was 92.4% RP and 92.2% BT, there was no statistical difference reported for clinical or age variables.	RP group: role physical functioning, bodily pain, social functioning and role emotional functioning was worse at 1 month but recovered at 3 months. Mental health scores improved over baseline after 6 months. BT group general HRQoL domains were not affected and did not change from baseline. General health domain of HRQoL was better in the RP than the BT group (P=0.031). RP group experienced urinary, bowel and sexual dysfunction 1 month. BT group experienced urinary and bowel dysfunction but non-significant. General and mental health scores were lower in the BT participants than the RP participants at 12 months. LIMITATIONS: Possible bias of HT and use of sexual aids. Selection bias is also possible.
Spry et al., (2006)	Assess the intermittent	PARTICIPANTS: N=250	DESIGN: Prospective longitudinal.	9 months of HT led to worsening of 22 of the 23 scales with most dramatic declines reported in the first 3 months. The only

Australia 22/22 100% – B3	effect of androgen blockade for men with PC.	DEMOGRAPHICS: **Age** <70 years N=86 (34.4.%), 70-79 years N=130 (52%), >80 years N=34 (13.6%), **Marital** married N=210 (84%) CLINICAL: Locally advanced N=66 (26.4%), locally recurrent N=116 (46.4), Metastatic N=34 (13.6%)	TIME POINTS: Baseline (before treatment) and then every 3 months for 3 years. MEASURES: Demographic and clinical data, EORTC-C30 +PR25 ATTRITION: Response rate of the questionnaires was 80%. .	clinically significant difference was reported for sexual function, hot flushes, sleep disturbances and loss of maleness. Higher baseline testosterone was associated with a greater weight gain, no other scales were influenced. 9 months period of HT was associated with simultaneous and progressive deterioration of broad ranges of HRQoL domains. During androgen recovery (off the HT) there was a slight improvement, smaller magnitude and slower recovery, taking approx 9-12 months. Increasing age was associated with poorer function. However, disease staging did not predict changes in HRQoL following HT. LIMITATIONS: Selection bias is possible, the use of sexual aids were not reported, thus a possible bias.
Inoue et al., (2009). Japan 19/20 95% – B3	Assess HRQoL over 5 years from men treated with RP.	PARTICIPANTS: N=194 DEMOGRAPHICS: **Age** 50-59 N=10 (5.2%), 60-69 N=80 (41.2%), 70-79 N=102 (52.6%), >80 N=2 (1%). No further demographics reported. CLINICAL: All staging T1-T3, Nerve-sparing 59%	DESIGN: Prospective longitudinal. TIME POINTS: Baselines (before RP), 3 and 6 months, 1, 2, 3, 4, 5 years after RP. MEASURES: Age and clinical data, SF-36 and UCLA-PCI ATTRITION: Response rates 100%, 82.1%, 86.2%, 87.4%, 86.6%, 79.7%, 75% at baseline, 3 and 6 months, 1, 2, 3, 4, 5, years, respectively.	SF-36: decrease in role limitation due to physical problem and social functioning at 3 months but recovered at 6 months. Year 2 and 3, role limitations due to physical and emotional problems, mental health scores were significantly better than baseline values. Urinary function significantly worsened at 3 months for 49% of the participants and improved at baseline scores at 5 years for 92% of participants. Bowel domains were not affected by the RP. Significant predictor of recovery of sexual function was NS surgery, not age. LIMITATIONS: Selection bias is possible and the use of sexual aids was not reported as this would have influences sexual function.
Rees et al., (2005) UK 19/22 86% – B3	Assess response shift (RS) in HRQoL in participants with advanced PC.	PARTICIPANTS: N=55 participants and N=43 partners consented. DEMOGRAPHICS: **Age** 72.9 mean (SD 8.5) years. No further demographics reported. CLINICAL: **PSA** range 4.4 to 5050ng/mL, median 57.2 ng/mL, N=13 with distant metastasis, N=44 locally advanced disease. N=44 treated HT only, N=8 RP in additional to neoadjuvant HT, N=3 no treatment either AS/WW.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (at diagnosis) 3 and 6 months MEASURES: Age and clinical data, Prostate Cancer Patient and Partner Questionnaire. ATTRITION: N=55, N=2 participants died, leaving a total of N=53 and N=41 partners that completed all data collection points.	Partners of participants reported significantly higher cancer-related distress at all time points compared to participants. Advanced prostate cancer predicted worse HRQoL at 3 and 6 months. The method of testing response shift was using retrospective questionnaires then comparing the magnitude of difference in actual and retrospective responses. HRQoL evaluated over a longitudinal study identified response shift (changing internal standards of HRQoL (recalibration) and redefinition of HRQoL (reconceptualization). LIMITATIONS: It is not clear whether there is evidence of response shift, or whether this change was a result of memory recall bias. Selection bias is possible.
Roberts et al., (2006)	Assess the impact of	PARTICIPANTS: N=93	DESIGN: Prospective longitudinal.	Social support did not predict physical functioning, but significantly predicted better mental functioning. Social support

USA 20/20 100% - B3	social support on HRQoL for men with localized PC.	DEMOGRAPHICS: **Age** 65.7 mean (SD 6.48) years, **Race** white 91%, **Employment** working 52.8%, retired 47.2%, **Education** college and higher 60.6%, **Marital** married 85.4%. CLINICAL: RP 61.8%. BT 18%, RT 13.5%, BT and RT 4.5%	TIME POINTS: baseline (close to after treatment was complete) and 3 months follow-up MEASURES: Demographic and clinical data, SF-36, adapted Impact of Events Scale (measuring intrusive thoughts), 2 questions "How often have you found yourself searching to make sense of your illness? How often have you found yourself wondering why you got cancer or asking why me?" (Searching for meaning variables). Social Provisions Scale (SPS) – perceived support. ATTRITION: N=93, N=89 (96%) response rate.	and negative coping were not related to physical functioning. Social support at T1 was positively and significantly related to T2 mental functioning (β=4.08,SE β=2.01 P<0.05), accounting for 5% of the variance. T1 social support was negatively associated with T1 negative coping(β=-0.50, SE =0.15, P<0.01). Negative coping mediated the relationship mediated the relationship between T1 social support and T2 mental functioning. Men with higher perceived social support predicted of better mental functioning. LIMITATIONS: Biased in favour of white and well-educated, thus a limits the generalizability of the findings. Men may have also wanted to represent themselves in a socially desirable way, if they did not have adequate support or lower mental health. Selection and attrition bias are possible.
Robinson et al., (2006) Canada 20/22 90% – B3	Assess HRQoL for participants treated with salvage cryosurgery.	PARTICIPANTS: N=46 consented. DEMOGRAPHICS: **Age** 70 mean (range 57-79) years. No further demographics reported. CLINICAL: Failure of RT and were treated with cryotherapy N=12 were treated with HT, PSA mean <10 ng/mL before cryosurgery, 12 and 24 PSA <0.3 ng/mL for 87% of participants.	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before cryosurgery), 6 weeks, 3, 6, 12, 18, 24 months after treatment. MEASURES: Age and clinical data, EORTC-C30, PCI ATTRITION: Response rate ranged from baseline 97.8%, to 24 months 83.8%. Differences between responders and non-responders were not reported.	Bowel dysfunction significantly worsened at 6 weeks but returned to baseline scores by 24 months. No statistically significant differences in baseline scores and 24 months scores for any domains of the C30. Main long-term effect of treatment reported was urinary and sexual function problems. LIMITATIONS: Selection and attrition bias is possible. Demographic data was not reported, known predictors of HRQoL.
Monga et al., (2005) USA 18/20 90% – B3	Assess HRQoL in men treated with RT.	PARTICIPANTS: N=89, N=62 consented DEMOGRAPHICS: **Age** 67.8 mean (range 55-78) years, **Education** mean number of years of education was 12.4 (range 6-18) years, **Marital** married N=28 (70%) CLINICAL: All participants had localized PC. The intent for RT was for curative treatment.	DESIGN: Prospective longitudinal TIME POINTS: baseline (before RT), mid-way through RT, completed RT, 4 weeks after RT and 8 weeks after RT. MEASURES: Demographic and clinical data, FACT-P, Becks Depression Inventory (BDI), Epworth Sleepiness Scle (ESS), Piper Fatigue Scale (PFS) ATTRITION: N=62, N=22 had incomplete data, data was reported comparing responders and non-responders .	N=18 (45%) developed mild to moderate symptoms of proctitis during RT. Physical well-being worsened mid-way through RT, complete RT and at 4 weeks after treatment and 8 weeks. No significant changes in the depression scores at any of the follow-up time points. A significant relationship was found between depression and overall HRQoL. Prostate cancer-specific HRQoL significantly worsened mid-RT, complete RT and 4 weeks. At 8 weeks the scores returned to pre-RT levels and were significantly higher (P=0.001), suggesting improvement symptoms. LIMITATIONS: There was not a control group for comparisons, and the follow-up was limited. There was not an individual break down for the prostate cancer-specific domain, overall score.
Ball et al., (2006) USA 21/22 95% -	Assess short-term HRQoL for 5 surgical approached	PARTICIPANTS: N=719. Open RP, (ORP) N=135 LRP N= 124	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (pre-surgery), 1, 3 , 6 months	Urinary function significantly worsened for ORP, LRP, dVP at 1 month. The overall percentage of participants return of continence (ORP 38%, LRP 25%, dVP 39%, P=0.03) this favouring earlier return of continence after ORP and dVP. At 1 month, BT

B3	for treating men with localized PC.	Da Vinci robotic prostatectomy (dVP) N= 82 103Pd (BT) N= 118 Prostate Cryoblation N= 39 DEMOGRAPHICS: **Age Group 1** ORP 59 mean (SD 6) years, LRP 61 mean (SD 7), dVP 60 mean (SD 7), **Group 2** BT 67 mean (SD7), PCryo 72 mean (SD 7). **Race** white ORP 76%, LRP 79%, dVP 83%, BT 75%, PCryo 76%. No further demographics reported. CLINICAL: Non-nerve sparing surgery was performed OPR 30%, LRP 54%, dVP 22%, HT was given only to 23% of BT participants, 28% of PSryo participants. Participants were all T1-T3	MEASURES: Demographic and clinical data, UCLA-PCI and the AUA-SI. ATTRITION: N=719, N=498 included in the analysis. Response rates of participants completing at least one data collection ranged from 95% to 27%	participants reported worse urinary function and urinary irritative and obstruction, worse bowel function, and worse sexual function. 1 month, PCryo group also reported worse urinary function and irritative and obstruction urinary symptoms, worse bowel and sexual function. At 3 months, ORP, LRP and dVP reported worse sexual function, the percentage of patient returning to baseline score (ORP 27%, LRP 21%, and dVP 31%, favouring dVP). 3 months, BT reported an improvement in bowel function, but reduced sexual function was still significant. For the PCryo group, urinary obstructive and irritative symptoms improved, significantly worse bowel and sexual function. 6 months all treatment groups <50% of participants returning to baseline scores for urinary, bowel and sexual function. A trend of improvement can be seen, however still a large proportion of patient managing dysfunction. LIMITATIONS: Selection and attrition bias are possible.
Truong et al., (2006) Canada 18/22 81% – B3	Assess the impact of fatigue and HRQoL for men treated with RT.	PARTICIPANTS: N=28 DEMOGRAPHICS: **Age** median 69 years (range 57-84). No further demographics reported. CLINICAL: Majority of participants had T2 and T3 (46% and 32%, respectively), median Gleason was 7 (range 6-10), median PSA at diagnosis was 9.0 ng/mL (range 2.5-103). All participants were treated with HT median duration was 12.2 month (range 2.5-103 ng/mL)	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before RT), mid-way through RT (3-5 weeks during), end of RT, median 6.5 weeks after RT. MEASURES: Age, clinical data, Brief Fatigue Index. ATTRITION: There was no attrition reported in this study.	Fatigue significantly worsened during RT, the end of RT and 6.5 weeks follow-up compared to baseline. Fatigue predicted worsening general activity, mood, walking ability, normal work, relation to others and enjoyment of life. The scores were significantly lower than baseline (peaked severity at the end of RT), improved at the 6.5 weeks follow-up, but were significantly worse than baseline (P=0.009). At the end of the RT 71% reported some degree of fatigue. LIMITATIONS: Selection bias is possible. This influence of HT had the potential of interfering with participants reports of fatigue, as a side effect of HT, rather than RT.
Nguyen et al., (2009) USA 18/22 81% – B3	Assess HRQoL for participants treated with salvage BT.	PARTICIPANTS: N=25 DEMOGRAPHICS: **No demographics reported** CLINICAL: No participants received HT with the salvage BT. All men had T1 to T2 disease, maximum Gleason of 7, 92% PSA <10ng/mL.	DESIGN: Prospective longitudinal. TIME POINTS: Baseline (before salvage BT), 3, 15, 27 months after treatment. MEASURES: Clinical data, prostate specific HRQoL questions (not named in this paper, reports validity). ATTRITION: 80% of the participants completed all of the data collection questionnaires. No significant differences between the responders and non-responders.	Sexual dysfunction significantly worsened at 27 months compared to baseline. At baseline 14/22 (64%) had at least partial erections firm enough for penetration, but by 27 months, only 4/22 (18%) had erections firm enough for penetration (P=0.005). Urinary obstruction/irritation, significantly worsened at 3 months and was non-significant at 27 months. Bowel dysfunction significantly worsened overtime to 15 months but was no longer significant at 27 months. Gradual decline in sexual function at all follow-up periods. For urinary and bowel symptoms, generally there was an acute worsening of symptoms until 15 months, but at the 27 months follow-up improvement in

				these side-effects were identified. LIMITATIONS: Limited follow-up, as toxicity maybe have developed after 27 months, for example one patient developed a rectourinary fistula requiring colostomy/urostomy at 29 months. Small N. Selection bias is also possible.
Prezioso et al., (2007) Italy 21/22 95% – B3	Assess HRQoL for men treated with HT modalities.	PARTICIPANTS: N=587 DEMOGRAPHICS: **Age** median 73.3. No further demographics reported. CLINICAL: Median time after diagnosis was 21.7 months. 42.9% treated with LHRH and AA combined therapy, 31.2% LHRH only, 24.6% AA only.	DESIGN: Prospective longitudinal. TIME POINTS: At enrolment, 6 and 12 months after enrolment. MEASURES: Age and clinical data, EORTC-C30 ATTRITION: 548/587 completed baseline having at least 3 months HT, 499/587 completed 6 months data collection, 471/587 completed 12 months data collection.	Anti-androgen (AA) monotherapy was significantly associated with a better HRQoL than LHRH treatment in all functional scales but emotional function. Worsening physical function and general health status was observed in all groups, however, AA had significantly better HRQoL than LHRH treatments. LHRH is associated with reduced HRQoL, particularly physical function, energy, general health status. AA had a better HRQoL profile than LHRH. LIMITATIONS: Other previous main PC treatments (for example RP) are possible in this patient group, thus introduced bias in their reports of HRQoL. Selection bias is possible. Demographics were not reported known predictors of HRQoL.
Kouba et al., (2007) USA 18/22 81% - B3	Assess short-term HRQoL for men treated with RP.	PARTICIPANTS: N=121 DEMOGRAPHICS: **Age** African American (AA) 60.7 mean years, Caucasian Americans (CA) 60.6 mean years, **Race** AA N=38 (31%), CA N=83 (69%). No further demographics reported. CLINICAL: PSA mean 8.4ng/mL, estimated blood loss (EBL) 493 mls during operation, Short-term complications <30 days N=10 urinary retention, haematuria, pelvic haematoma, AF, DVT.	DESIGN: Prospective longitudinal TIME POINTS: Baseline (before RP), 1, 2, 3, 4, 5, 6 weeks after surgery. MEASURES: Demographic and clinical data, SF-12 ATTRITION: Overall return rate of the questionnaire was 80%, but once missing data was taken into account, approx 60% of the data was usable for analysis.	Physical component significantly worsens at 6 weeks. Physical component did not differ by race; however age had a significant association with the physical component. At baseline younger men <60 had a higher physical component than older men (59.4 vs. 54.8 respectively, P<0.0001). Mental component significantly improved over baseline scores up to 6 weeks. Mental component at baseline was significantly lower for African Americans compared to white ethnic background, but was no longer significant at 6 weeks This study did not find PSA, clinical stage or pathological stage a significant predictor of HRQoL components. LIMITATIONS: This study did not use a disease-specific HRQoL measure, to evaluate the changes in urine, bowel sexual dysfunction during this acute stage. Selection and responder bias is possible. Limited demographics reported and confounders are possible.
Hedestig et al., (2005) Sweden 13/16 81% – B3	Explore participants' experiences of living after a LRP.	PARTICIPANTS: N=10 DEMOGRAPHICS: **Age** range 61-69 years, **Marital** N=9 married N=1 widowed, All were retired. CLINICAL: All treated with LRP, no co-morbidities that	DESIGN: Qualitative – narrative interviews – Content Analysis. TIME POINTS: Cross-sectional interviews, 30-60 minutes in the participants' home. Audio-recorded and kept reflective diary.	Main themes emerged, becoming a changed man, striving to gain a sense of control in a new life situation, managing a new life situation, striving to become reconciled to the new life situation. Losing their erectile function radically changed their sex life, which gave them a sense of grief. Losing erections men expressed detracting from their manliness. Most of the men said that they

		affected daily life, had surgery between >6 months and <3 years.	MEASURES: Examples of questions; what did it mean for you to receive a diagnosis of PC? What is your experience of having been operated on for PC? Probing questions such as what do you mean? What did you do? Tell me about your thoughts and feelings?	did not feel like a "whole man." Men reported having to wear daily pads as a result for urinary incontinence. Some men changed their clothes several times a day despite pads. They described living a social life was something impossible to do. To try and maintain urinary incontinence men focused on consumption of drinks, toilets visits, how they dressed in cold weather, and how they avoided stressful situations and activities that could worsen their incontinence. They also reported worries about the odour from their wet pads when people were around them. PSA testing gave men a sense of control over their progression of their illness. 2 men did not understand why they needed their PSA checked since their prostate gland had been removed. LIMITATIONS: The results can't be generalized however the meaning of the men's experience can be a useful insight to further understanding of issues around men HRQoL after RP. The theoretical framework to guide this study was not reported.
Ames et al., (2008) USA 18/20 90% – B3	Explore the psychological need of men with biochemical recurrence of PC.	PARTICIPANTS: N=28 DEMOGRAPHICS: **Age** 76 mean (range 58-87), **Race** white 86%, black 14%, **Education** College and above 72%, **Marital** married/partner 85%, **Employment** retired 88%. CLINICAL: For RT recurrence is defined as 3 consecutive rises in PSA >0.2 ng/mL, or a substantial rise that triggers hormone therapy. Surgical recurrence is a PSA level greater than 0.2ng/mL.	DESIGN: Mixed methods (focus groups and questionnaire based). The questionnaires were compared to normative data. TIME POINTS: Completion of the questionnaire immediately before the focus group. MEASURES: Focus groups, 2 hour focus groups containing 4-6 men per group. Semi-structured focus group guide, audio recorded and conducted by an experienced moderator. Demographic and clinical data, FACT-P, SF-36, Profile of Mood States – Brief (POMS-B), Life Experiences Survey, Perceived Stress Scale	From the FACT-P the sample had a lower physical well-being (23.6, SD 4.7) thank normative data (26.2, SD 2.8) P<0.0001. However, this sample reported higher emotional well-being (20.3, SD 3.5) with normative data 23.5 (4.3) P<0.0001.Similar result were reported for the SF-36, general health and emotional well-being were higher than normative samples (P<0.05 and P<0.01, respectively). The themes identified from the focus groups were; 1) **Meaning of quality of life** , no limitations in activities, maintenance of good social relationships, ability to remain active both physically and mentally, freedom from health problems, including side-effects, *Representative quote:* "the extent to which one's life conforms to the norm…doing those things that a person with reasonable health enjoys" 2) **Physical effects of prostate cancer**, decreased libido and erectile function, hot flashes from hormone treatment, frequent urination and incontinence, fatigue, loss of muscle strength, *Representative quote:* "Sex life is zero". 3) **Psychological effects of prostate cancer**, anxiety about recurrence/location of cancer in the body, anger, knowing that there is no cure, physical side effects of treatment (e.g. fatigue, sexual dysfunction, hot flashes, incontinence) causes anxiety and distress, *Representative quote:* "It's always on

				the back burner" 4) **Impact of PSA testing on quality of life**, anxiety about PSA testing, anxiety about recurrence, anxiety in circumscribed to 12-24 hour period prior to testing, *Representative quote:* "Every time it (PSA) went up, it threw me into dithers". 5) **Strategies used to cope with prostate cancer**, social support from friends and family, particularly from spouse, use of distraction (e.g. staying busy with work, hobbies, volunteering), Use of health denial (i.e. positive avoidance), exercise and strength training, making healthier diet choices (reduced fat, increased soy), *Representative* quote: I"I just accepted it…it's there…I just don't think about it anymore…I don't fight it". LIMITATIONS: Small sample size, therefore limits the generalisabilty of the findings. The individual patient's treatments were not reported, and therefore might have influenced their reports of HRQoL The normative sample comparisons were difficult to make meaningful comparison, for example the population for the PSS is an undergraduate sample of students.

Appendix 2.1 Extracted Data for Social Support Review

Ordered by study design

First author and year (quality assessment)	Aim	Participants	Method	Findings
Carmack Taylor et al., (2006) USA 26/32 81% - B2	Evaluating the efficacy of a group based lifestyle programme to improve HRQoL - 3 groups	PARTICIPANTS: N=1093 approached, N=134 participants consented. DEMOGRAPHICS: **Age** 69.2 years (range 44.8-89.0). **Race** white 73.1%, Black/African American 20.1%, Other 6.7%. **Employment** 54.4% retired, 40.3% working, 6.7% other. **Education** College degrees or advanced degree 76%. **Marital** married 82.8%. CLINICAL: At baseline participants has been on the androgen-ablation therapy average of 32.7 months. N=46 allocated to the Lifestyle programme. N=51 allocated to the Education Support N=37 Standard Care. ALLOCATION: Adaptive allocation, which takes in to account study participants characteristics, aimed at achieving a better group balance. Allocation taken into account QoL, BMI and time on HT. Randomized by statistician or data manager.	DESIGN: Intervention study/Quasi experimental TIME POINTS: Baseline, 6 months and 12 months. MEASURES: Demographic/clinical data, SF-36, Centres for Epidemiological Studies (CES-D), State Scale of the State/Trait Inventory (STAI) Brief Pain Inventory (Short Form), Interpersonal Support Evaluation List (ISEL), 7-Day physical Activity Recall, Stage of Motivational Readiness for Physical Activity, Process for Change of Physical Activity, Decisional Balance for Physical Activity Questionnaire, Physical Activity Self-Efficacy Questionnaire. Six-minute walk test, Body Mass Index (BMI) Attrition: Overall, 6 months data was collected in 83%, 12 months 84% of the sample. INTERVENTION: Approx 8 men per group. Orientation session and then for 6 months 16 weekly sessions, and 4 biweekly sessions, lasting 1 and half hours each for each intervention group. **Lifestyle Programme**: Participants encouraged to take regular exercise, though self-monitoring, goal-setting, overcoming barriers, understanding their caloric intake and exercise expenditure. No physical activity was undertaken other than demonstration of exercises. **Educational Support**: Topic included by group discussion was diet and prostate cancer, side-effects of androgen-ablation and sexuality. **Control group:** Standard Care.	No intervention effect was identified on HRQoL. There were no significant differences between HRQoL at 6 or 12 months between the groups (across all the components of the measures). Social support did not significantly change (increase) at 6 or 12 months follow-up. Mediation of social support and physical activity analysis were not performed because QOL did not change (DV of interest). LIMITATIONS: Validity and reliability was not reported on all the measures. It was reported that the sample size lacked power to run the study analysis. Bias is possible as a result of the allocation process
Carmack Taylor et al., (2007)	Secondary analysis of lifestyle	See publication above (number 1) for participant details.	See publication above (number 1) for participant details.	At 6 months, participation in a group (lifestyle or educational support) benefited those with greater distress (anxiety and depression) or with limited support, compared to the control group.

USA 26/32 81% – B2	intervention			
Weber et al,. (2004) USA 26/28 92.8% B2	To evaluate the effect of a Dyadic intervention (one-to-one)	PARTICIPANTS: N-100 approached, N=51 refused, N=21 excluded for various. N=32 (N=2 withdrew due to fear of incontinence), final sample N=30 DEMOGRAPHICS: **Age** 58, range 48-67 years), **Race** white 82%, **Martial** 79%, **Education** high school and higher 85%, **Employed** 62%. CLINICAL: All men radical prostatectomy 6 weeks post-surgery ALLOCATION: Randomisation procedure was not described	Methods: intervention study/Quasi experimental TIMEPOINTS: 6 weeks, 4 weeks and 8 weeks MEASUREMENTS: Modified inventory of social support, Stanford inventory of cancer patient adjustment (self-efficacy), Geriatric depression scale, UCLA Prostate cancer index, Charleston Index, Satisfaction with intervention written by supportive partners INTERVENTION: Supportive partners long-term survivors of prostate cancer (9 white 1 black), mean age 68.2 years, stable PSA for year prior to the study, men underwent a 2 hour training session. Each dyad met 8 times during an 8 week period.	There were no significant differences in social support or HRQoL. LIMITATIONS: Sample was mostly white, married and educated. High refusal for participants (potential for selection bias).
Scholz (2008) Germany 21/22 95.4% - B3 12	To test, moderating role of social support on HRQOL .	PARTICIPANTS: Men treated by LRP and their partners N=77 DEMOGRAPHICS: **Age** 61.6, SD 6.03 years**, Education** 48.4% reported 9-10 years of education, **Employment** 58.9% retired CLINICAL: All men treated by LRP.	DESIGN: Prospective longitudinal survey TIMEPOINTS: 2 weeks and 6 months after surgery MEASURES: Received social support was measured by 2 subscales from the Berlin Social support scale (BSSS), spouses provided social support, 2 items from the BSSS, SF-12 ATTRITION: T2 response rate was 81.8%.	There were no main effects of received or provided social support on HRQOL. A moderating effect was found which identified those men who had low mental or physical HRQoL at BL had better HRQoL at 6 months when received social support was high at BL. LIMITATIONS: Small sample size, limited question items to assess social support.
Roberts et al, 2006 USA 18/18 - B3	Examine the influence of social support on HRQoL	PARTICIPANTS: N=93 DEMOGRAPHICS: **Age** 49.1-76.9 years, 65.7, SD 6.48 years, **Ethnicity** white 91%, Employment 50.6% employed, 47.2% retired, **Marital** 84.5% married CLINICAL: Time since treatment range 7-120 days, mean 46.7 days RP 61.8%, BT 18%, EBRT 13.5%, BT and EBRT 4.5%. All had localised disease.	DESIGN: Prospective longitudinal survey TIMEPOINTS: BL (close after treatment was completed), and 3 months follow-up MEASURES: Demographic variables, SF-36, Impact Events Scale (intrusive thoughts), Searching for meaning (2 items questions), Social Provisions Scale (perceived social support). ATTRITION: N=93, 96% completed questionnaires at the time points.	T1 social support was positively related to T2 HRQoL (β=4.08, P<0.05) accounting for 5% of the variance. Social support was negatively and significantly related to coping (β=-.50, P<0.01). Coping and social support accounted for 24% of the variance of HRQoL. A reduction of the strength of T1 social support with T2 HRQoL due to T1 coping Sobel test (Z=2.84, P=0.004) LIMITATIONS: Did not have a representative sample for men from minority groups. Limited follow-up.
Kershaw et al, 2008 USA 18/22 81% -	To test the stress and coping model	PARTICIPANTS: N=429 patient-spouse dyads approached. N=46 did not meet inclusion, N=120 declined, leaving N=263 consented (68.7%).	DESIGN: Prospective longitudinal survey TIMEPOINTS: BL (consent), 4 and 8 months.	Participants with more BL social support used more positive coping at 8 months. Coping and appraisal was found to predict HRQoL. Social support did not have a main effect on HRQoL.

B3		DEMOGRAPHICS: **Ethnicity** white 86%, **Marital** length of marriage was 31.8, SD 14 years, CLINICAL: N=121 control newly diagnosed 67%, advanced disease 20%, biochemical recurrence 13%.	MEASURES: SF-12, Brief COPE, Appraisal of illness or appraisal of Caregivers, Personal resource Questionnaire (perceived social support), Lewis Mutuality and Interpersonal Sensitivity Scale (communication about the illness) Symptom distress scale (general symptom distress) ATTRITION: N=134 control group, 90% completed 8 months.	LIMITATIONS: The sample was mostly white, wealthy and educated.
Andel et al 2004 Netherlands 22/22 100% -B3	Explore psycho-social factors in relation to HRQoL	PARTICIPANTS: N=138, total number of men approached was not reported. DEMOGRAPHICS: RP **Age** 62.1, SD 5.8, **Marital** 88.9%, EBRT **Age** 70.0, SD 6.2, **Marital** 90.7%. CLINICAL: N=65 RP, N=73 EBRT.	DESIGN: Prospective longitudinal survey TIMEPOINTS: BL (before treatment) 1 year MEASURES: Socio-economic, EORTC C30 (general HRQoL), International Prostate Score (urine), Incontinence, Sexual Behaviour Questionnaire, EORTC CR38 (bowel function), Utrecht Coping List, Profile of Mood states, Impact of Event Scale, Expression and non-expression of emotions, Social support Questionnaire (perceived social support), Life Experience Survey (life events). ATTRITION: N=138 completed BL, N=129 completed 1 year (93% response).	HRQoL was significantly related negative coping and social support (spearmen rank correlations). No moderation or mediation analyses were performed. LIMITATIONS: Limited assessment of social support and selection bias is possible.
Visser et al, 2003 Amsterdam 21/22 95% -B3	To explore the psycho-social factors the influence HRQoL	PARTICIPANTS: N=84. Number of participants approached was not reported. DEMOGRAPHICS: **Age** 63.3 years, range 65-75 years, **Marital** married 83%, **Education** no education or primary education 45%. CLINICAL: N=23 PC (clinical profiles not known), N=37 BPH.	DESIGN: Prospective longitudinal survey TIMEPOINTS: Before diagnosis, 3 months after completion of BL. MEASURES: Socio-economic data, EORTC C30+PR25 (HRQoL), International Profile Symptom Score (IPSS) (urinary function), Sexual Behaviour Questionnaire (sexual function), Standardised COPE (coping), Profile of Mood States (distress), Life Experience Survey (Life events), Social Support Questionnaires (Perceived social support), Social desirability, Health Behaviours (smoking, drinking, etc.) ATTRITION: PC N=31 BL, N= 23 (74.2%) returned 3 months questionnaires, BPH N=51 BL, N=38 (74.5%) returned T2. There were no significant differences between responders and non-responders.	Diagnosis is the most important factor to influence a significant decline in HRQoL after 3 months for men suffering from PC. HRQoL was also associated with social support and positive coping. HRQoL decreased for men with PC, but remained stable overtime for men with BPH. LIMITATIONS: Small sample size, lack of treatment information for men with PC. Selection bias is possible.
Zhoe et al 2010 USA 17 - 85% -B3	To test the relationship with social support and perceived stress on HRQoL	PARTICIPANTS: N=175 DEMOGRAPHICS: **Age** 64.8 (SD 7.5), **Marital** 84% married/partner, **Ethnicity** white 40%, Hispanic, 41%, African American 18%. CLINICAL: Localised PC, Surgery 48%, EBRT 52%.	DESIGN: Prospective longitudinal survey TIMEPOINTS: BL (study consent), 3, 10 months and 2 years. BL approximately 15.5 (SD 6.2 since diagnosis. MEASURES: Demographic variables, Perceived Stress Scale (PSS), Social Support Instrument (ESSI [perceived social support]), FACT-G (HRQoL) ATTRITION: Selection and attrition bias were not reported in this study.	Greater social support at BL significantly predicted higher HRQoL (physical well-being) scores at 2 years (β=.16, P<0.05. The results indicated that partial mediation between the relationship of social support and HRQoL partially mediated by perceived stress (sobel test=1.99, P<0.05) LIMITATIONS: BL reports prior to treatment were no measured, thus BL within this study are likely to not

Zhou et al, 2010 USA 19/22 86% - B3	To test mediation, whether PS mediates the relationship between SS and HRQoL.	PARTICPANTS: N=180 DEMOGRAPHIC: **Race** White 40%, Hispanic 41%, African American 19% **Age** 64.9 SD **7.5: Marital Status** 84% married: **Education** in years 13.7 SD 3.4 CLINICAL: Months since Tx 10.6 SD 4.8: Months since diagnosis 15.4 SD 6.2: RP 48%, EBRT 52%. Localised PC. **Excluded** if on HT or Hx of other cancers.	Same study as above	accurately capture change over time throughout the patient trajectory. Limited evaluation of other social support elements, selection and attrition bias are possible. Excluded participants with psychological co-morbidity. Mediation: HRQoL was associated with social support (β=.053, P<0.001, positive coping was associated with social support (β=0.36, P<0.01). Partial mediation results indicated the relationship between social support and HRQoL was partially mediated by positive coping (Sobel test z = -2.29, <0.05). Moderation was not performed. LIMITATIONS: as above
Poole et al, 2001 Canada 13/20 65% - C1	Explore the effect of social support groups on HRQoL	PARTICIPANTS: Men recruited through 13 prostate cancer support groups in Columbia, Canada. N=240 (60%) selection rate for support groups, (55%) for men approached In clinics. DEMOGRAPHICS: Majority of men were white, married and retired and had postsecondary education. **Age** 67.7, SD7.9 years. CLINICAL: Time since diagnosis was 27 months, SD 34.7.	DESIGN: Cross-sectional survey TIMEPOINTS: Various stages of the cancer journey MEASURES: Perceptions of support survey-patient version (perceived social support), Social support questionnaire, perceived social support (social network and satisfaction), FACT-P, Coping (adapted measure 4 items), Demographic data. ATTRITION: N/A.	Attenders were more likely to source information from fellow participants and non-attenders were more likely to rely on medical staff. No significant differences were found between attenders and non-attenders for positive coping, HRQoL, or satisfaction with their social support. LIMITATIONS: Cross-sectional design, lack of clinical information, frequency of attenders using the support group was not reported and may have biased the results.
Rondorf-Klym et al 2003 USA 16/22 72% - C1	To explore the influence of psycho-social factors on HRQoL	PARTICIPANTS: N=132 mailed out, N=97 (response (73%), N=88 completed in the analysis DEMOGRAPHICS: **Age** 66 years (SD not reported), large majority of men were married/partner 84%, and had high level of education CLINICAL: RP 12-24 months after surgery	DESIGN: Cross-sectional survey TIMEPOINTS: 12-24 following RP. MEASURES: UCLA-Prostate cancer index, Rosenberg self-esteem scale, anger suppression scale, personal resource questionnaire 85 part 2, Centre for epidemiological studies questionnaire, multidimensional health locus of control, The Quality of life scale. ATTRITION: N/A.	Perceived social support had a main effect on HRQoL. It was reported that social support was a mediator variable for HRQoL. However, it is not clear/not reported identifying the independent variable, for which social support mediated the relationship. LIMITATIONS: Cross-sectional design and lack of clarity on the strategies to test for mediation effects of social support.

		T1or T2 disease staging.		
Mehnert et al 2009 Germany 19/24 79% - C1	Examine perceived stress, social support on HRQoL	PARTICIPANTS: N=511. Number of participants approached was not reported. DEMOGRAPHICS: **Age** 64 years **Marital** 88% married, **Education** High school 66%, **Employment** 68% retired. CLINICAL: All RP, time since surgery was 27 months (mean), ranging from 2 to 141 weeks. Sample – all stages of cancer.	DESIGN: Cross-sectional survey TIMEPOINTS: Varying time post diagnosis. MEASURES: Posttraumatic Stress Disorder checklist, Illness Specific Social Support, SF-8, HADS. ATTRITION: N/A.	Married men had significantly higher perceived social support compared to single men (P<0.0001). Social support has a main effect on HRQoL . LIMITATIONS: Selection bias is possible, limited assessment of social support, cross-sectional design.

Appendix 3.1 Extracted Data for Self-Management Review

Ordered by study design

Author (year) Quality score	Aim	Participants (demographics and clinical data)	Methods (Study Design, sampling method)	Overall findings and limitations
Wilson et al,. (2010) USA B2 14/26 53.8%	Interventions study (3 groups) designed to promote self-care behaviours	PARTICIPANTS: N=70 consented the total number of participants approached was not reported. DEMOGRAPHICS: Race 60% African American, 38% white; Age 67.4 (SD 7.1) years; Education years of education was 13.3 years CLINICAL: Men treated with EBRT. No additional clinical data was reported.	DESIGN: Quasi-experimental design TIMEPOINTS: Baseline (pre-treatment), mid-treatment (3 weeks into EBRT), final treatment and 3 and 6 month follow-up. MEASURES: Rapid Estimate of Adult Literacy in Medicine (REALM [adult literacy in healthcare]), Side-effect Interview (Dodd, 1982), Self-care Management Techniques checklist (Mood and Bickes, 1992 [instrument further developed based on Dodd work). ATTRITION: no attrition reported. CONTROL (usual care) n=24. EDUCATION (N=24) intervention delivery at pre-treatment, treatment and post treatment (post-treatment not defined). Educational video covering the following topics 1) introduction to EBRT, 2) side-effects, 3) emotional reactions, this was supplemented by written easy to read written instructions. EDUCATION AND CONTRACTING GROUP (N=23) same educational intervention with the addition of mutually agreed goals (relating to physical, emotional and social side effects) formed as a written contracted agreed and discussed with the nurse and the patient. Goals achieved were rewarded (e.g. skin care products, movies, oral product, etc.). The contracted was reviewed weekly by the nurse and patient.	Mean of 8 EBRT side-effects were reported, with a min of 1 and max of 27 reported symptoms. Side-effects onset developed at 11 days (SD 6) into EBRT and lasted from approx 8 days. Severity of symptoms 2.8 (mean, SD 0.6), ranged from 1.0 to 4.3 (5 point scale, with 5 being the most severe). The intervention and literacy levels did not have any association with the symptom. Most common side effects reported were: skin reactions, dietary problems, emotional reactions and fatigue. Maintaining skin integrity was reported by n=52 and used on average 2 out of 5 self-care behaviours, most common reported "was avoiding exposure of treated area to direct sunlight". Self-care diet was reported in n=57, and used 5 of the 12 self-care options, most common " eating foods high in protein", reducing risk of infection by avoiding crowds and with people with colds and washing hands often" Self-care for emotional adjustment was reported in n=53, they reported using 6 of the 12 self-care options. Most frequently reported self-care was "making a special effort to maintain a positive attitude and consciously trying to think more positively". 60% of participants reported taking more rest periods as self-care strategies to alleviate fatigue. The number of self-care actions significantly increased overtime from BL to 6M (12.2, SD 7.0 vs. 13.9 SD 6.1; t=1.94, P=.05). LIMIATIONS: Selection and attrition bias are possible. No description of the randomization procedure. The increase of self-care behaviours could have been related the progression of symptoms overtime and not was a result of the interventions as the authors suggest.

Oliffe et al,. (2009) Canada B3 28/30 93.3%	To describe the self-care strategies for men undertaking active surveillance.	PARTICIPANTS: N=45 approached, N=25 consented (reasons for non-participation are described but differences were not identified by statistical analysis). DEMOGRAPHICS: Age 48-77 years mean 68 (SD not reported); Marital majority of men married (n=19), Education (n=19) completed postsecondary education. No further demographic information provided. CLINICAL: Low-risk cancer, Men been on AS for less than 2 years. PSA≤10, Gleason score ≤6 cancer stage localised disease.	DESIGN: Qualitative, cross-sectional design. Interpretive description, constant comparison, data analysis facilitated by NVivo. Questions examples: "what as the AS experience been like for you?", "How as the AS impacted on your lifestyle?" When do you feel pressured to make a treatment decision, and how to you cope with that?" TIMEPOINTS: Different trajectories but majority less than 2 years on the AS programme. ATTRITION: N/A.	Overarching theme of "Uncertainly" emerged "…when you are told you have cancer, I mean it sticks with you, cancer is cancer, I don't care if I have low grade or not and nobody could tell me that there's no cancer growth there, there's no, um, spreading of cancer, they can't tell men that, which really frustrates me". The self-care management of uncertainty was managed by 2 strategies "living a normal life" and "doing something extra". The theme of living a normal life reflected men's positions to view their cancer as benign (n=14) "get out of jail free card". The 2nd emergent theme for self-care was men's accounts of "doing something extra", which could focus on dietary modifications " to go on AS has more to do with diet change…it goes hand in hand". Men reported eating less, taking supplements including saw palmetto, green tea, tomatoes, pomegranate juice. LIMITATIONS: Cross-sectional design, likely that man's self-care actions will change overtime. Specific understandings how self-care changes with and between men overtime time would not be explored. Potential for disparity with self-reports and men's actual self-care behaviour.
Hamm, et al,. (2000). UK C1 9/22 40.9%	To assess feasibility and participants experiences of self-injecting hormone therapy.	PARTICPANTS: N=20 consented; total number approached was not reported. DEMOGRAPHICS: Age 70.9 (SD not reported) 53-85 years, No additional demographic information was presented. CLINICAL: excluded if they had life expectancy < 6 months, needle phobia, or GP was reluctant for them to participate.	DESIGN: Prospective longitudinal survey. TIMEPOINTS: Different trajectories, but all assessed over 5 visits (1, 2, 3, 4, 12 months). MEASUREMENTS: EORTC C30, HADS, PSA and testosterone levels (to measure compliance). ATTRITION: n= 6 participants withdrew from the study at the first visit, n= 1 after the second visit, n-1 after 4th visit due to long standing alcohol problems, n=1 died, N=11	No significant changes in the HADs and C30 were reported. Actual statistical tests and results were not reported, testing of the groups between those who continued and those individual who did not were not reported. Men self-injection demonstrated good compliance. Men injected 5 times over 12 months. The results identified the potential a group of participants to administer HT via injection. No additional self-care was reported in this publication. LIMIATIONS: Selection and attrition bias are possible. No description about the statistical approach to the analysis of HRQoL or anxiety and depression scores overtime. No data was presented for HRQoL or HADS. Self-efficacy was not measured a potential bias in accounting for self-injection compliance.
Mroz et al,. (2010) Canada B3 26/28 92.8%	To explore men's perceptions of their diet following a prostate cancer diagnosis.	PARTICIPANTS: N=14 total number approached not reported, mainly convenience sampling. DEMOGRAPHICS: Age range 48-78 years, mostly retired, college educated and middle class. CLINICAL: Variation in treatment modalities, cancer	DESIGN: Grounded theory qualitative methodology. Cross-sectional design. Social constructive perspective, constant comparison, triangulation (interviews, food journals and field notes) TIMEPOINTS: Diagnosed with prostate cancer no longer than 5 years MEASUREMENT: Individual semi-structured interview lasting 60-90 minutes	A decision for men to make a diet change as a self-care behaviour was complex involving multiple factors; pre-cancer diet perceptions, diet and health understandings, perceptions of prostate cancer, and their need to "do something" for self-care. Cancer was viewed as a chronic condition required on-going management and therefore expressed needs to "do something" about it. "…PSA shows up well then I'll probably get a little excited again and then go on, figure out what to do. But then I'll probably start learning a lot more about fine-tuning my diet or whatever…"

		trajectory.	conducted in the participants home, food diary (paper and pen record of eating events over 1 week), and field notes. ATTRITION: N/A	Overall perceptions influenced the dietary eating habits and included a number of sub-themes: 1) already had a healthy diet; "I've always eaten healthily and I will continue to eat healthily but I'm not expecting it to cure cancer", 2) diet does not affect prostate cancer recovery "It's not a disease that once you have got it diet's going to do much for you". 3) Won the war, "you might as well go out and do what you want", 4) diet and health understandings, "I want to live a longer life and I want to live it well in the absence of disease. And diet is one of the few things I can do that would help". Men described a variety of dietary patterns. 4 main themes emerged "eating as usual", "intensifying efforts", "adding on", "overhauling diet" LIMITATIONS: Demographics homogeneity limits the transferability of the findings. Research context was a nutritional student which may have influenced the findings for health and eating.
Kim (2011) Korea B2 18/20 93.3%	Intervention study (2 groups) to promote self-care and quality of life	PARTICPANTS: N=69 consented total number approached was not reported. DEMOGRPAHICS: Age majority 61-70 years; mostly high school education or less; approximately equal distributions for employed and unemployment CLINICAL: All men treated for radical prostatectomy. Homogeneity of the control and experimental group was reported across clinical and demographic variables.	DESIGN: Quasi-experimental, intervention study. TIMEPOINTS: Pre-surgery, during intervention and post intervention (2 months after surgery). MEASUREMENTS: Self-as-Career Inventory (measurement of self-care capability), Adapted tool based on the self-care activity measurement tool, TACT-P. CONTROL: n=34: INTERVENTION: n=35 educational (symptoms management, catheter management, self-care of urinary incontinence, post-surgery exercise, diet and defecation, pelvic floor and biofeedback). Materials included written and visual information provisions. 1st visit (pre-op 1 month/30mins) 2nd visit (3-4 weeks pre-op/30 mins) 3rd visit (pre-op 1 day/60mins) 4th visit (2-3 days post-op/60mins) 5th visit (5-7 days post op/60mins) 6th visit (1 month post-op/90mins)	The interventional group reported higher self-care capabilities compared to the control group, analysis based on before and after intervention. Self-care activity scores (using the self-care activity measurement tools) identified no significant differences in self-care behaviours between the 2 groups. The actual self-care strategies were not reported. Self-care agency (self-care capability) – men who participated in the intervention reported higher self-care agency compared to the control group. There was no significant difference in the quality of life scores across both groups. The items from the FACT-P were not reported. LIMITATIONS: A longer evaluation of intervention effect is needed. Unclear what the "control groups" provision of nursing care involved. There was no randomization to the control/intervention group. Selection bias is possible.

Appendix 4.1 Study Consent Form

REC Number: 10/S1402/7
Patient Identification Number for this study:

CONSENT FORM

Title of Project: Exploring prostate cancer patients' self-management demands and social support experiences using questionnaire and behavioural diaries: Does support buffer the relationship between coping and HRQoL?

Name of Researcher: Catherine Paterson **Please initial box**

1. I confirm that I have read and understand the information sheet dated 20/03/2010 (Version 3) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Dundee or from NHS Tayside, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my personal contact details being kept by researchers directly involved in this study, so that the researcher can contact me to deliver relevant follow-up questionnaires. ☐
5. I agree to my GP being informed of my participation in the study. Should my questionnaires reveal that I am at risk of having anxiety and depression I agree to my GP being informed. ☐
6. I agree to complete the questionnaire pack for this study at consent and at 6 months follow-up in the post. ☐
7. I agree to complete the electronic diary for this study. I understand the diary section will involve a brief 30 minute interview after completion of the diary. ☐
8. I agree to the audio recording of this interview. ☐

Name of Patient Date Signature

Researcher Date Signature

Appendix 4.2 Participant Information Sheet

PARTICIPANT INFORMATION SHEET

'Exploring prostate cancer patients' self-management demands and social support experiences using questionnaire and behavioural diaries: Does support buffer the relationship between coping and health-related quality of life (HRQoL)?

(A study exploring self-care demands and the effects of social support in prostate cancer patients)

My name is Catherine Paterson and I am required to undertake a project as part of my Ph.D. course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.

Aim

The present study aims to find out whether social support affects patient's health and adjustment to having a prostate cancer. The findings from the present study will help to advise healthcare professionals on the self-care activities that men with prostate cancer carry out, how patients cope, and the impact that different types of social support can have on patients. Self-care means actions that people take to improve health, prevent further disease, and improve symptoms.

Why have I been invited?

You are being asked to participate as you have recently been diagnosed with prostate cancer. Your surgeon has identified that you would be eligible to help us with this.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect my medical care.

What will happen if I agree to help?

If you agree to take part in this study it will involve you filling in questionnaires and the option of completing an electronic diary. The first questionnaire will be given to you in person after you consent, and we will then send you the same questionnaire 6 months later. A prepaid envelope will enable you to send back your questionnaires to the research nurse. The questionnaires will ask a number of questions regarding

how you are feeling. All your responses will be treated entirely confidentially. However, if you feel unable to answer any parts of the questionnaire, that will not be a problem. If you feel that you need to discuss your responses with someone, the study nurse will be available to help you. If you consent, we will collect all the other data we need related to your cancer diagnosis from your case notes.

The second stage of the study is optional, you will be asked by the research nurse involved in the study whether you would agree to complete an electronic diary for a total of 1 month. Only a small number of patients, who agree to complete the diary, will actually be selected to go on and complete the diary. The participants selected to complete the diary will be based on the stage of their cancer and existing social support.

If you are selected to complete the electronic diary, the research nurse involved in this study will contact you to explain how to use it, and provide an opportunity to ask questions. The completion of the electronic diary will be for a maximum of 1 month, and you will be prompted to complete the diary 3 times per day as you go about your usual activities. The diary asks you about how you are feeling, your self-care activities and what social support experiences you have had. The diary will prompt you to complete the diary midmorning, late afternoon and night time. The precise timing of the diary entries may be different for each individual depending on their daily self-care routines; the aim is to make the timing of the diary as convenient as possible for the person completing the diary. On completion of the electronic diary after 1 month, the research nurse involved in this study will interview you to ask you about your experiences of having, and completing the electronic diary. With your permission, we would like to audio record the interview so that we have an accurate account of what was said. A contact telephone number will be given so that you can contact the research nurse directly should you need help or have questions whilst completing the diary.

There should be no harmful effect on you if you choose to participate in the study. The information we gather may not benefit you directly, but we hope that it will be of help in the future to people with the same condition.

Should your response to the questionnaires reveal that you are distressed, with your permission we would like to inform your GP.

What if there is a problem?

If you have a concern about any aspect of the study, you should speak to the researchers who will do their best to answer your questions. The contact details are listed below. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Dundee who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager, Complaints Office, Ninewells Hospital (Freephone 0800 027 5507). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Tayside but you may have to pay your legal costs.

Who will disclose, use and/or receive my health information?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Identifiable data will be stored for 6-12 months after the study has ended, and unidentifiable data will stored for 5 years. All study data will be stored safely and securely in a locked filing cabinet in a locked room at the University of Dundee. If participants decided to withdraw from the study all identifiable data will be withdrawn, however, unidentifiable data will be retained.

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinizing all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Tayside and the Regulatory Authorities, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. Once the results are ready we hope to publish them in a medical journal so that other healthcare professionals can benefit from the results. At the end of the study, we will send you a newsletter describing the results of the study.

The study has been organised and co-coordinated at the School of Nursing and Midwifery, Dundee University.

Contact
For further information/help regarding this study please contact: *Catherine Paterson the Research Nurse*
(Chief Investigator) Tel 01382 388645 Email: c.x.paterson@dundee.ac.uk

If you are unhappy about any aspect of the study please contact Dr Martyn Jones supervisor of this research
Tel 01382 388656 *Email: m.c.jones@dundee.ac.uk*

Thank you for considering taking part

Appendix 4.3 Case Record Form

Study Number:

BASELINE DEMOGRAPHIC DETAILS			
Name:			
Address:		**GP:**	
Postcode:			
Date of entry:			
Age at study entry:			
Date of birth:			
CHI number:			
Marital Status: Single Married Divorced Separated Widowed Co-habiting			
Employment: In employment/self-employed ☐ Retired ☐ Student ☐ Seeking work ☐ Other ☐ ……			
What age did you leave school?			
Do you have any of the following? (Tick all that applies)			
SD/O levels	☐	**BA**	☐
Highers/A levels	☐	**BS/BA (Hons.)**	☐
SVQ	☐	**MSc**	☐
NC	☐	**Ph.D.**	☐
HNC	☐	**Trade qualification/equivalent**	☐
HND	☐		

Nationality:

Willing to complete PDA – EMA? **Yes** ☐ **No** ☐

Reason for not willing to complete:

Study Number:

BASELINE CLINICAL DATA

Cancer details:

Prostate:

Localised ☐ *Locally Advanced* ☐ *Metastatic* ☐

Watchful waiting ☐ RRP ☐ Perineal Prostatectomy ☐

Laparoscopic Prostatectomy ☐ Brachytherapy ☐ Radical Radiotherapy ☐

Hormone Manipulation ☐ Active Surveillance ☐ Cryotherapy ☐

High Intensity Focused Ultrasound ☐ Chemotherapy ☐ Other ☐

Pathological Stage (pre-op) :

Pathological Stage (post-op):

Date treatment started:

PSA:

Date Cancer Diagnosed:

CO-MORBIDITIES	**(Circle)**	
Diabetes	Yes	No
Depression	Yes	No
Myocardial Infarction	Yes	No
Angina	Yes	No
Cerebrovascular Disease/Stroke	Yes	No
Peripheral Vascular Disease	Yes	No
Chronic Obstructive Airways Disease(Asthma or COPD	Yes	No
Multiple Sclerosis	Yes	No

Other……..

Neurological Disorder: state……

Other Malignancies: state…….Year diagnosis…….

Additional Cancer Support

1. Do you use a Prostate Cancer Support Group? (Tick all that applies)

Dundee Group ☐ Perth Group ☐ Fife Group ☐

If 'yes' how often do you use this centre?

Several times weekly ☐ Several times monthly ☐ Monthly ☐
Every several months ☐ Yearly ☐

2. Do you use the Maggie's Centre? (Please tick to indicate your answer)

Yes ☐ No ☐

If 'yes' how often do you use this centre?

Daily ☐ Several times weekly ☐ Several times monthly ☐ Monthly ☐
Every several months ☐ Yearly ☐

Please indicate the type of support services you use at the Maggie's Centre:
(please tick all that apply)

Benefits Advice ☐
Online Forum ☐
Support Group
Men at Maggie's Group ☐
Prostate Cancer Networking Group ☐
Individual Psychology Session ☐
Relaxation Therapy ☐
Art/Writing Workshop ☐
Drop-In (Informational/Support Session) ☐

3. Do you use any other cancer support services? Yes ☐ No ☐

If 'yes' please describe this cancer support service……..……
……

How often do you use this cancer support service?

Daily ☐ Several times weekly ☐ Several times monthly ☐ Monthly ☐
Every several months ☐ Yearly ☐

Study Number:

6 MONTHS CLINICAL DATA

Cancer details:

Prostate:

Localised ☐ *Locally Advanced* ☐ *Metastatic* ☐

Watchful waiting ☐ RRP ☐ Perineal Prostatectomy ☐

Laparoscopic Prostatectomy ☐ Brachytherapy ☐ Radical Radiotherapy ☐

Hormone Manipulation ☐ Active Surveillance ☐ Cryotherapy ☐

High Intensity Focused Ultrasound ☐ Chemotherapy ☐ Other ☐

Change to treatment: Yes ☐ **No** ☐

Pathological Stage (pre-op) :

Pathological Stage (post-op):

Date treatment started:

PSA:

CO-MORBIDITIES	**(Circle)**	
Diabetes	Yes	No
Depression	Yes	No
Myocardial Infarction	Yes	No
Angina	Yes	No
Cerebrovascular Disease/Stroke	Yes	No
Peripheral Vascular Disease	Yes	No
Chronic Obstructive Airways Disease(Asthma or COPD)	Yes	No
Multiple Sclerosis	Yes	No

Other…….

Neurological Disorder: state…….

Other Malignancies: state…….Year diagnosis……

Appendix 4.4 Letter of Invitation

Mr C Goodman
Urology Department
NHS Tayside
Ninewells Hospital
Dundee

Date:

Dear NAME

INVITATION TO TAKE PART IN A RESEARCH STUDY – TITLE 'Exploring prostate cancer patients' self-management demands and social support experiences using questionnaire and behavioural diaries: Does support buffer the relationship between coping and HRQoL?'

I note that it is coming up for approximately 1 month after your diagnosis. You have an outpatient appointment on DATE, TIME and VENUE. I would like to bring to your attention a research study that you may be interested participating in. This study is looking at how social support may affect patients' health, and how patients cope with having a prostate cancer. This study will inform us of the best types of social support that can help patients. I have attached a Patient Information Sheet about the research study that will enable you to decide; whether or not you would like to take part. This research has been designed and is being undertaken by **Catherine Paterson (Research Nurse)** based at the University of Dundee.

If you are interested in taking part in the study, Catherine will be available to discuss this further at your clinic appointment. If you decide then to participate, Catherine will ask you some questions and give you some questionnaires whilst you are attending the clinic. Please complete the reply slip enclosed as appropriate to indicate if you are considering participating in this study. Please hand the reply slip to the receptionist on arrival at your urology appointment, and Catherine will arrange to discuss the study further. Should you wish to speak with Catherine directly before this appointment, her telephone number is **01382 388645**, please feel free to contact her at any time.

Thank you for your time and consideration for this research.
Yours sincerely

Mr Goodman
Consultant Urologist Surgeon
Enc: Patient Information Sheet, Reception Reply Slip

Reply Slip to be handed to the receptionist on arrival at my urology clinic appointment on [DATE and TIME].

I

_____

___ agree/do not agree* to meet with Catherine Paterson (Research Nurse) to discuss the study further with a view to take part.

I understand that this will take an additional 20 mins (approximately) of my time at the clinic. During this time, I understand that I will have the opportunity to ask questions and have the study explained further. If I agree to take part, I will sign a study consent form, and Catherine will do her first data collection.

* Delete as appropriate.

Mr C Goodman
Urology Department
NHS Tayside
Ninewells Hospital
Dundee

Date

Dear NAME

INVITATION TO TAKE PART IN A RESEARCH STUDY – TITLE 'Exploring prostate cancer patients' self-management demands and social support experiences using questionnaire and behavioural diaries: Does support buffer the relationship between coping and HRQoL?'

I note that it is coming up for approximately 1 month after your diagnosis. I would like to bring to your attention a research study that you may be interested in participating in. This study is looking at how social support may affect patients' health, and how patients cope with having a prostate cancer. This study will inform us of the best types of social support that can help patients. I have attached a Patient Information Sheet about the research study that will enable you to decide whether or not you would like to take part. This research has been designed and is being undertaken by **Catherine Paterson (Research Nurse)** based at the University of Dundee.

If you would like to participate in this study, we would like to offer you an appointment on Friday DATE, at TIME, VENUE. At this time, Catherine will discuss the study further, and if you then agree to take part will ask you to complete some questionnaires. Can you please complete the reply slip enclosed to indicate whether or not you agree to attend this appointment. If this time is not suitable, but you would like to meet with Catherine about this study, please leave your telephone number and she will contact you at home to arrange this appointment. Catherine's telephone numbers is **01382 388645**, if you have any questions about this study, please feel free to contact her at any time.

Thank you for your time and consideration for this research,
Yours sincerely

Mr Goodman
Consultant Urologist Surgeon
Enc: Patient Information Sheet, Reply Slip and pre-paid envelope

Reply Slip to be returned in the pre-paid envelope.

I

_____

___ agree/do not agree* to meet with Catherine Paterson (Research Nurse), on Friday, at TIME, at the urology clinic, HOSPITAL to discuss the study further with a view to take part.

If this time is not suitable, but you would like to meet with Catherine to discuss the study please leave your telephone number so that she can contact you to arrange this.

My Telephone number _____

I understand that the appointment with Catherine will take 20 mins (approximately) of my time at the clinic. During this time, I understand that I will have the opportunity to ask questions and have the study explained further. If I agree to take part, I will sign a study consent form, and Catherine will do her first data collection.

* Delete as appropriate.

Appendix 4.5 GP Letter

Catherine Paterson
Research Nurse
School of Nursing and Midwifery
11 Airlie Place
Dundee
DD1 4HJ

01382 388645

[STUDY NUMBER]

Dear [Dr FIRST, SURNAME]

Title ''Exploring prostate cancer patients' self-management demands and social support experiences using questionnaire and behavioural diaries: Does support buffer the relationship between coping and HRQoL?
(REC: 10/S1402/7)

[RE: Patients name, address, DOB, CHI)

The above research study aims to determine the effect of social support on health outcomes (quality of life/anxiety and depression) and better understand the self-care activities for men who are diagnosed with a prostate cancer. Your patient has agreed to take part in the study which will involve completing questionnaires (baseline and 6 months follow-up), with the opportunity to complete the second optional stage of the study. The second stage of the study is the completion of an electronic behavioural diary for 1 month. Only small number (12) patients will actually be selected to complete the behavioural diary as individual single-case studies.

We would be extremely grateful if you could help us by sticking the label provided on their notes and contacting Tel: **01382 388645** should any significant events occur, for example, death of a patient, or change of address.

Please find enclosed a copy of the consent and patient information sheet for your records. Please do not hesitate to contact me if you would like any further information about the study or to discuss the participation of your patient.

Yours sincerely

Catherine Paterson
(Research Nurse, CI)

Enc: Patient Information sheet and study consent form

Appendix 4.6 GP Letter Notifying the HADS Scores

Catherine Paterson
Research Nurse
School of Nursing and Midwifery
11 Airlie Place
Dundee
DD1 4HJ

Telephone: 01382 388645

[STUDY NUMBER]

Dear [Dr FIRST, SURNAME]

Title ''Exploring prostate cancer patients' self-management demands and social support experiences using questionnaire and behavioural diaries: Does support buffer the relationship between coping and HRQoL?
(REC: 10/S1402/7)

[RE: Patients name, address, DOB, CHI)

This patient has agreed to take part in the above study. As part of this research your patient completed a number of questionnaires assessing social support, health-related quality of life, self-care activities and anxiety and depression. In particular, the Hospital Anxiety and Depression Scale (HADS) provide a brief state of measure for both anxiety (7 question items) and depression (7 question items). This tool facilitates the detection of clinical cases of anxiety and depression. On evaluation of [Name] questionnaire it was identified that they may be at risk of having anxiety and depression, the results from evaluation are as follows:

HADS Results:

Depression: ☐ ***Borderline 8-10***
Anxiety: ☐ ***Borderline 8-10***

Your patient is aware that I am writing to you informing you of their results. If you would like to discuss this further, or require further information please don't hesitate to contact me on telephone number **01382 388645.**

Yours sincerely

Catherine Paterson
(Research Nurse, Chief Investigator)

Appendix 4.7 Six Months Questionnaire Cover Letter

Catherine Paterson
Research Nurse
School of Nursing and Midwifery
11 Airlie Place
Dundee
DD1 4HJ

Telephone: 01382 388645

[STUDY NUMBER]

Dear [TITLE, FIRST, SURNAME]

Study 'exploring self-care demands and the effects of social support in prostate cancer patients: 6 months follow-up questionnaire'

Thank you very much for your time, effort and continued participation in the above study. Please find enclosed your six months follow-up questionnaire and a pre-paid envelope. I would be extremely grateful if you could complete the questionnaire as best as you can, and return it to me at your earliest convenience in the pre-paid envelope.

Your participation in this research has now ended following completion of this questionnaire. I would also like to take this opportunity to express my sincere thanks for your help, as without your time and effort this research would not have been possible.

Once the findings from the study are concluded, a newsletter informing you for the study findings will be available.

Thank you very much for you time and help, it is greatly appreciated.
Yours sincerely

Catherine Paterson
(Research Nurse, Chief Investigator)

Appendix 4.8 Fourteen Day Questionnaire Reminder Cover Letter

CATHERINE PATERSON
RESEARCH NURSE (CI)
SCHOOL OF NURSING AND MIDWIFERY
11 AIRLIE PLACE
DUNDEE
DD11 4HJ

Telephone: 01382 388645

[DATE]

[STUDY NUMBER]

Dear [TITLE, FIRST, SURNAME]

A study exploring self-care demands and the effects of social support in prostate cancer patients: Questionnaire Reminder

According to our records we have not yet received your study questionnaire. I would be grateful if you could complete the enclosed questionnaire and return it to me in the pre-paid envelope. However, if you have completed your questionnaire and sent it back to me, please ignore this letter and accept my apologies for any inconvenience caused.

Thank you very much again,

Yours sincerely

Catherine Paterson
(Research Nurse, Chief Investigator)

Appendix 4.9 Study Questionnaires

Questionnaire Pack

Social support and self-care in prostate cancer patients

Study Number:

Initials:

Date:

Return to:
Catherine Paterson
Chief Investigator
11 Airlie Place
School of Nursing and Midwifery
Dundee University
Dundee
DD1 4HJ
Telephone: 01382 388645

Hospital Anxiety and Depression Scale

This questionnaire is designed to help your clinician know how you feel. Ignore the numbers printed on the left of the questionnaire. Read each item and **underline** the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response.

A **I feel tense or 'wound up':**
3 Most of the time
2 A lot of the time
1 From time to time, occasionally
0 Not at all

D **I still enjoy the things I used to enjoy:**
0 Definitely as much
1 Not quite as much
2 Only a little
3 Hardly at all

A **I get a sort of frightened feeling as if something awful is about to happen:**
3 Very definitely and quite badly
2 Yes, but not too badly
1 A little, but it doesn't worry me
0 Not at all

D **I can laugh and see the funny side of things:**
0 As much as I always could
1 Not quite so much now
2 Definitely not so much now
3 Not at all

A **Worrying thoughts go through my mind:**
3 A great deal of the time
2 A lot of the time
1 From time to time but not too often
0 Only occasionally

D **I feel cheerful:**
3 Not at all
2 Not often
1 Sometimes
0 Most of the time

A **I can sit at ease and feel relaxed:**
0 Definitely
1 Usually
2 Not often
3 Not at all

D **I feel as if I am slowed down:**
3 Nearly all the time
2 Very often
1 Sometimes
0 Not at all

A **I get a sort of frightened feeling like 'butterflies' in the stomach:**
0 Not at all
1 Occasionally
2 Quite often
3 Very often

D **I have lost interest in my appearance:**
3 Definitely
2 I don't take as much care as I should
1 I may not take quite as much care
0 I take just as much care as ever

A **I feel restless as if I have to be on the move:**
3 Very much indeed
2 Quite a lot
1 Not very much
0 Not at all

D **I look forward with enjoyment to things:**
0 As much as ever I did
1 Rather less than I used to
2 Definitely less than I used to
3 Hardly at all

A **I get sudden feelings of panic:**
3 Very often indeed
2 Quite often
1 Not very often
0 Not at all

D **I can enjoy a good book or radio or TV programme:**
0 Often
1 Sometimes
2 Not often
3 Very seldom

Now check that you have answered all the questions

For office use only:
D: ☐ *Borderline 8-10*
A: ☐ *Borderline 8-10*

MAC Scale

INSTRUCTIONS: A number of statements are given below which describes people's reactions to having cancer. Please circle the appropriate number to the right of each statement, indicating how far it applies to you at present. For example, if the statement definitely does **not** apply to you, then you should circle 1 in the first column.

	Definitely does **not** apply to me	Does **not** apply to me	Applies to me	Definitely applies to me
1. I have been doing things that I believe will improve my health e.g. changed my diet.	1	2	3	4
2. I feel I can't do anything to cheer myself up.	1	2	3	4
3. I feel that problems with my health prevent me from planning ahead.	1	2	3	4
4. I believe that my positive attitude will benefit my health.	1	2	3	4
5. I don't dwell on my illness.	1	2	3	4
6. I firmly believe that I will get better.	1	2	3	4
7. I feel that nothing I can do will make a difference.	1	2	3	4
8. I've left it all up to my doctors.	1	2	3	4
9. I feel that life is hopeless.	1	2	3	4
10. I have been doing things that I believe will improve my health e.g. exercising.	1	2	3	4
11. Since my cancer diagnosis, I now realize how precious life is and I'm making the most of it.	1	2	3	4
12. I've put myself in the hands of God.	1	2	3	4
13. I have plans for the future e.g. holidays, jobs, housing.	1	2	3	4
14. I worry about the cancer returning or getting worse.	1	2	3	4
15. I've had a good life; what's left is a bonus.	1	2	3	4
16. I think my state of mind can make a lot of difference to my health.	1	2	3	4
17. I feel that there is nothing I can do to help myself.	1	2	3	4

	Definitely does **not** apply to me	Does **not** apply to me	Applies to me	Definitely applies to me
18. I try to carry on my life as I've always done.	1	2	3	4
19. I would like to make contact with others in the same boat.	1	2	3	4
20. I am determined to put it all behind me.	1	2	3	4
21. I have difficulty in believing that this happened, to me.	1	2	3	4
22. I suffer great anxiety about it.	1	2	3	4
23. I am not very hopeful about the future.	1	2	3	4
24. At the moment I take one day at a time.	1	2	3	4
25. I feel like giving up.	1	2	3	4
26. I try to keep a sense of humour about it.	1	2	3	4
27. Other people worry about me more than I do.	1	2	3	4
28. I think of other people who are worst off.	1	2	3	4
29. I am trying to get as much information as I can about cancer.	1	2	3	4
30. I feel that I can't control what is happening.	1	2	3	4
31. I try to keep a very positive attitude.	1	2	3	4
32. I keep quite busy, so I don't have time to think about it.	1	2	3	4
33. I avoid finding out more about it.	1	2	3	4
34. I see my illness as a challenge.	1	2	3	4
35. I feel fatalistic about it.	1	2	3	4
36. I feel completely at a loss about what to do.	1	2	3	4
37. I feel very angry about what has happened to me.	1	2	3	4
38. I don't really believe that I had cancer.	1	2	3	4
39. I count my blessings.	1	2	3	4
40. I try to fight the illness.	1	2	3	4

QLQ – C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or suitcase?	1	2	3	4
2	Do you have any trouble taking a long walk?	1	2	3	4
3	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4	Do you need to stay in bed or a chair during the day?	1	2	3	4
5	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

	During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
6	Were you limited in doing either your work or other daily activities?	1	2	3	4
7	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8	Were you short of breath?	1	2	3	4
9	Have you had pain?	1	2	3	4
10	Did you need to rest?	1	2	3	4
11	Have you had any trouble sleeping?	1	2	3	4
12	Have you felt weak?	1	2	3	4
13	Have you lacked appetite?	1	2	3	4
14	Have you felt nauseated?	1	2	3	4
15	Have you vomited?	1	2	3	4

	During the past week:	**Not at all**	**A little**	**Quite a bit**	**Very much**
16	Have you been constipated?	1	2	3	4
17	Have you had diarrhoea?	1	2	3	4
18	Were you tired?	1	2	3	4

19	Did pain interfere with your daily activities?	1	2	3	4
20	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21	Did you feel tense?	1	2	3	4
22	Did you worry?	1	2	3	4
23	Did you feel irritable?	1	2	3	4
24	Did you feel depressed?	1	2	3	4
25	Have you had difficulty remembering things?	1	2	3	4
26	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27	Has your physical condition or medical treatment interfered with you social activities?	1	2	3	4
28	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions, please circle the number between 1 and 7 that best applies to you

29 How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

EORTC QLQ - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week	**Not at all**	**A little**	**Quite a bit**	**Very much**
31. Have you had to urinate frequently **during the day**?	1	2	3	4
32. Have you had to urinate frequently **at night**?	1	2	3	4
33. When you felt the urge to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34. Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	1	2	3	4
35. Have you had difficulty going out of the house because you needed to be close to a toilet?	1	2	3	4
36. Have you had any unintentional release (leakage) of urine?	1	2	3	4
37. Did you have pain when you urinated?	1	2	3	4
38. **Answer this question only if you wear an incontinence aid.** Has wearing an incontinence aid been a problem for you?	1	2	3	4
39. Have your daily activities been limited by your urinary problems?	1	2	3	4
40. Have your daily activities been limited by your bowel problems?	1	2	3	4
41. Have you had any unintentional release (leakage) of stools?	1	2	3	4
42. Have you had blood in your stools?	1	2	3	4
43. Did you have a bloated feeling in your abdomen?	1	2	3	4
44. Did you have hot flushes?	1	2	3	4
45. Have you had sore or enlarged nipples or breasts?	1	2	3	4
46. Have you had swelling in your legs or ankles?	1	2	3	4

Please go to the next page

During the last 4 weeks…	**Not at all**	**A little**	**Quite a bit**	**Very much**
47. Has weight **loss** been a problem for you?	1	2	3	4
48. Has weight **gain** been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (eg dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

When completing the questions below, please think about what you do to look after yourself (self-care activities) since your diagnosis. Please circle the number which best describes your answer to the statements below.

Not at all true	**Barely true**	**Moderately true**	**Exactly true**
1	**2**	**3**	**4**

		Please circle your answer			
1.	I can always manage to complete self-care activities that are difficult for me.	1	2	3	4
2.	It is easy for me to stick to my self-care activities and make sure that I carry them out well.	1	2	3	4
3.	I am confident in carrying out my self-care activities.	1	2	3	4
4.	Thanks to my resourcefulness, I know how to handle difficult self-care problems.	1	2	3	4
5.	If I have problems with self-care, I can solve it if I invest the necessary effort.	1	2	3	4
6.	I can remain calm when facing difficulties with self-care because I can rely on my coping abilities.	1	2	3	4
7.	If a new challenge faces me with self-care I'm usually able to handle it.	1	2	3	4

Self Care Diary

We are interested in knowing about the actions (self-care) you take to look after yourself. We would like you to think about the things that you have done within the last month to improve the health difficulties you have faced with your prostate cancer experience.

*For each of the difficulties listed, please tick (✓) if this has been a problem for you. If you tick **NO**, go to the next page.*

*If you tick **YES**, please using the number ratings below and circle the number that best indicates how much relief each action worked in improving the problem.*

EXAMPLE

0 = Not used at all
1 = Used, but no relief
2 = Used, got a little relief
3 = Used, got some relief
4 = Used, got quite a bit of relief
5 = Used, was completely relieved

Took advice from the dietician.....	0	1	2	(1)	4	5

1. In the past month, have you had urine (water work) problems?

YES ☐ **NO** ☐

(If NO go to Q2 on next page)

If yes, please circle the number which best describes how well each action worked for you:

0 = Not used at all
1 = Used, but no relief
2 = Used, got a little relief
3 = Used, got some relief
4 = Used, got quite a bit of relief
5 = Used, was completely relieved

(Please circle your answer)

a)	Used absorbent pads/pants.....	0	1	2	3	4	5
b)	Used urine sheaths (application like a condom)……	0	1	2	3	4	5
c)	Used urine catheters.....	0	1	2	3	4	5
d)	Avoided constipation.....	0	1	2	3	4	5
e)	Drank plenty of water (2 litres or 3-4 pints per day)..	0	1	2	3	4	5
f)	Avoided or reduced liquids that may irritate my bladder such as caffeine based						

	drinks (e.g. coffee, coke)	0	1	2	3	4	5
g)	Did pelvic floor exercises....	0	1	2	3	4	5
h)	Did bladder retraining (kept record of urine passed times, and amounts, with the aim of increasing the length between toilet times	0	1	2	3	4	5
i)	Information seeking.....	0	1	2	3	4	5
j)	Had counselling.....0		1	2	3	4	5
k)	Followed advice from the physiotherapist....	0	1	2	3	4	5
l)	Followed advice from continence advisor.....	0	1	2	3	4	5
m)	Shared my feelings and thoughts……	0	1	2	3	4	5
n)	Avoided heavy lifting.....	0	1	2	3	4	5
o)	Other (please write in)_____	0	1	2	3	4	5

_____

2. In the past month, have you had bowel problems? **YES** ☐ ☐

(If NO go to Q3 on next page)

If yes, please circle the number which best describes how well each action worked for you:

0 = Not used at all
1 = Used, but no relief
2 = Used, got a little relief
3 = Used, got some relief
4 = Used, got quite a bit of relief
5 = Used, was completely relieved

(Please circle your answer)

a)	Used absorbent pads/pants.....	0	1	2	3	4	5
b)	Took medication (foams/suppositories)..	0	1	2	3	4	5
c)	Used anal plugs (from continence advisor)..... 0		1	2	3	4	5
d)	Took medication for the pain/discomfort	0	1	2	3	4	5
e)	Took anti-diarrhoeal medication.....	0	1	2	3	4	5
f)	Took rest/sleep naps.....	0	1	2	3	4	5
g)	Did pelvic floor exercises.....	0	1	2	3	4	5
h)	Kept a record of bowel movements, to make going to the toilet more predictable.	0	1	2	3	4	5
i)	Took advice from the dietician	0	1	2	3	4	5
j)	Took advice from the continence advisor.....	0	1	2	3	4	5
k)	Shared my feelings and thoughts……	0	1	2	3	4	5
l)	Found out information.....	0	1	2	3	4	5
m)	Changed eating habits (e.g. 6 smaller meals).....	0	1	2	3	4	5
n)	Changed diet.....	0	1	2	3	4	5
o)	Increased fluid intake.....	0	1	2	3	4	5
p)	Used comfort measures (hot water bottle)	0	1	2	3	4	5
q)	Used fibre supplements to make stools more bulky..	0	1	2	3	4	5
r)	Other (please write in)_____	0	1	2	3	4	5

Modified from Nail (1989)

3. In the past month, have you had erectile dysfunction (impotence) problems?

YES ☐ **NO** ☐ (If NO go to Q4 on next page)

If yes, please circle the number which best describes how well each action worked for you:

0 = Not used at all
1 = Used, but no relief
2 = Used, got a little relief
3 = Used, got some relief
4 = Used, got quite a bit of relief
5 = Used, was completely relieved

(Please circle your answer)

a)	Had counselling.....	0	1	2	3	4	5
b)	Took medication (e.g. Viagra, cialis).....	0	1	2	3	4	5
c)	Used injections or insertions (e.g. MUSE)	0	1	2	3	4	5
d)	Used a vacuum penis pump.....	0	1	2	3	4	5
e)	Tried to lose weight (if you are overweight)	0	1	2	3	4	5
f)	Took regular exercise.....	0	1	2	3	4	5
g)	Moderated alcohol intake.....	0	1	2	3	4	5
h)	Stopped smoking(if you smoked).....	0	1	2	3	4	5
i)	Took more rest/sleep.....	0	1	2	3	4	5
j)	Took advise from the specialist nurse....	0	1	2	3	4	5
k)	Took advice from the doctor.....	0	1	2	3	4	5
l)	Shared my feelings and thoughts…	0	1	2	3	4	5
m)	Found out information.....	0	1	2	3	4	5
n)	Found ways to reduce stress.....	0	1	2	3	4	5
o)	Other (please write in)_____	0	1	2	3	4	5

_____

4. *Use this space to list any other problems you have experienced in the past month, that have not been included already. If you did not experience any other prostate cancer related problems, please TICK ✓NONE.*

NONE ☐ *(Go to Question 5)*

a) Are you having any other problems associated with your prostate cancer (please write in)?

Problem *1.*

_____

_____

If you wrote in a problem, how severe is it?

Please TICK ✓

Not at all	☐
A little	☐
Moderately	☐
Quite a bit	☐
Extremely	☐

How frequent is the problem?

Please TICK ✓

once a month	☐
twice a month	☐
once a week	☐
3-4 times per week	☐
Daily	☐
Several times daily	☐

Please write in each action (self-care) you took to deal with the problem. Circle the number which best describes your use of each of the action you have listed below:

0 = Not used at all
1 = Used, but no relief
2 = Used, got a little relief
3 = Used, got some relief
4 = Used, got quite a bit of relief
5 = Used, was completely relieved

(Please circle your answer)

a)	_____	0	1	2	3	4	5
b)	_____	0	1	2	3	4	5
c)	_____	0	1	2	3	4	5
d)	_____	0	1	2	3	4	5
e)	_____	0	1	2	3	4	5

b) Are you having any other problems associated with your prostate cancer (please write in)?

Problem 2.

_____

_____

If you wrote in a problem, how severe is it?

Please TICK ✓

Not at all	☐
A little	☐
Moderately	☐
Quite a bit	☐
Extremely	☐

How frequent is the problem?

Please TICK ✓

once a month	☐
twice a month	☐
once a week	☐
3-4 times per week	☐
Daily	☐
Several times daily	☐

Please write in each action (self-care) you took to deal with the problem. Circle the number which best describes your use of each of the action you have listed below:

0 = Not used at all
1 = Used, but no relief
2 = Used, got a little relief
3 = Used, got some relief
4 = Used, got quite a bit of relief
5 = Used, was completely relieved

							(Please circle your answer)
f)	_____	0	1	2	3	4	5
g)	_____	0	1	2	3	4	5
h)	_____	0	1	2	3	4	5
i)	_____	0	1	2	3	4	5
j)	_____	0	1	2	3	4	5

5. In general, can you please TICK ✓to tell us who provided ideas, suggestions for your actions (self-care). Tick all responses that apply.

Partner _____
Family _____
Friends _____
Specialist nurses _____
Doctors _____
Other cancer patients_____
Physiotherapists _____
Other_____ (please write in)

Perceived Stress Scale

The questions in this scale ask you about feelings and thoughts during the **last month.** To complete the questions below, please circle the appropriate answer for how often you have felt or thought a certain way.

0 = Never 1 = Almost never 2 = Sometimes 3 = Fairly often 4 = Very often

1.	In the last month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2.	In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3.	In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4.	In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5.	In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6.	In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7.	In the last month, how often have you been able to control your irritations in your life?	0	1	2	3	4
8.	In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9.	In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10.	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

In the last 6 months have you experienced any life events for example (death of a spouse, moving house, birth of a grandchild, divorce, etc)?

Please List

_____

_____

_____

Berlin Social Support Scale (BSSS).

Please indicate using the scale below how much you agree with each statement over the last four weeks.

1= Strongly agree 2= Somewhat agree 3=Somewhat disagree 4=Strongly disagree

1.	There are some people who truly like me.	1	2	3	4
2.	Whenever I am not feeling well, other people show me that they are fond of me.	1	2	3	4
3.	Whenever I am sad, there are people who cheer me up.	1	2	3	4
4.	There is always someone there for me when I need comforting.	1	2	3	4
5.	I know some people upon whom I can always rely.	1	2	3	4
6.	When I am worried, there is someone who helps me.	1	2	3	4
7.	There are people who offer me help when I need it.	1	2	3	4
8.	When everything becomes too much for me to handle, others are there to help me.	1	2	3	4
9.	When I am down, I need someone who boosts my spirits.	1	2	3	4
10.	It is important for me always to have someone who listens to me.	1	2	3	4
11.	Before making any important decisions, I absolutely need a second opinion.	1	2	3	4
12.	I get along best without any outside help.	1	2	3	4
13.	In critical situations, I prefer to ask others for their advice.	1	2	3	4
14.	Whenever I am down, I look for someone to cheer me up again.	1	2	3	4
15.	When I am worried, I reach out to someone to talk to.	1	2	3	4
16.	If I do not know how to handle a situation, I ask others what they would do.	1	2	3	4

17. Whenever I need help, I ask for it. 1 2 3 4

Please think about the person who is closest to you when answering the following questions:

1= Strongly agree 2= Somewhat agree 3=Somewhat disagree 4=Strongly disagree

18. I kept all bad news from him/her. 1 2 3 4

19. I avoided everything that could upset him/her. 1 2 3 4

20. I showed strength in his/her presence. 1 2 3 4

21. I did not let him/her notice how bad and depressed I really felt. 1 2 3 4

22. I avoided any criticism. 1 2 3 4

23. I pretended to be very strong, although I did not feel that way. 1 2 3 4

Still thinking about the person who is closest to you, how did this person react to you during the last month?

1= Strongly agree 2= Somewhat agree 3=Somewhat disagree 4=Strongly disagree

24. This person showed me that he/she loves and accepts me. 1 2 3 4

25. This person was there when I needed him/her. 1 2 3 4

26. This person comforted me when I was feeling bad. 1 2 3 4

27. This person left me alone. 1 2 3 4

28. This person did not show much empathy for my situation 1 2 3 4

29. This person complained about me. 1 2 3 4

30. This person took care of many things for me. 1 2 3 4

31. This person made me feel valued and important. 1 2 3 4

32. This person expressed concern about my condition. 1 2 3 4

33. This person assured me that I can rely completely on him/her. 1 2 3 4

34. This person helped me find something positive in my situation. 1 2 3 4

35. This person suggested activities that might distract me. 1 2 3 4

36. This person encouraged me not to give up.	1	2	3	4
37. This person took care of things I could not manage on my own.	1	2	3	4
38. In general, I am very satisfied with the way this person behaved.	1	2	3	4

This question asks about people in your environment who provide you help or support. List all the people you know, excluding yourself, whom you can count on. Please write in their relationship to you (see example below).

Who can you really count on to care about you, regardless of what is happening to you?

EXAMPLE

1) **NO ONE** ☐ *tick (✓)* *2) Husband* *3) Daughter*

4) *Friend* 5) *Doctor* 6) *Reverent*

7) 8) 9)

Question 1

Who can you really count on to care about you, regardless of what is happening to you?

1) **NO ONE** *tick (✓)* *2)* *3)*

☐

4) 5) 6)

7) 8) 9)

Thank you very much.

Appendix 4.10 Steering Group Documentation

Steering Group Minutes

Meeting 3 (15th March, 2010)

Present: Catherine Paterson (CP) (chair)
Dr. Martyn Jones (MJ)
Dr. Janice Rattray (JR)
Andy Wallace (AW)
Bob Cromb (BC)
Cara Taylor (CT)

Apologies: Prof Billy Lauder

1. Apologies were given on behalf of the absentees. The minutes taken from the last meeting were agreed as being an accurate account for what was discussed.
2. CP provided a brief reminder introduction to the research background and methods.
3. CP identified that all the necessary approvals are secured for this research (sponsorship, ethics and R & D), with the funding for this research coming from Alliance for Self-Care Research.
4. CP has piloted the study materials. The questionnaire survey takes approx 15-20 minutes to complete with no large quantities of missing data. The diary has been piloted to 13 individuals so far. The Behavioural Diary User Guide has been modified as directed from the pilot.
5. The members from the group present discussed the paper copies of the research materials. The PIS had a few typographical errors, these will be corrected. Within the baseline demographics, the educational element will be further broken down, i.e. what age did you leave school, and listing the qualifications. Within the clinical data – 'Other' will be added to the co-morbid conditions. The additional cancer support services, requires modifications, adding in prostate cancer patient support group user, and clarity to the different support services at the Maggie's centre. CP will modify cancer support services sheet and email this around to the group members for comment.
6. The questionnaire pack will need to checked through 'word' by 'word' to ensure that there are no typographical errors present.
7. There were a few modifications to the questionnaire pack, CP contact details will be on the cover, with a few modifications to the self-care diary, rewording of the example, numbering the other self-care problems, and removing the initials from the network support question.
8. The group then discussed the diary. There was a consensus to change the anchors in several of the questions. The revised versions are as follows, coping – not at all and always, self-efficacy questions – not at all and always, self-care demand – not at all and extremely, control – not at all and completely, symptoms

– not at all and always, discussing thoughts and feelings – not at all and always. Within the incident entry the support questions were agreed to be modified to how much support did you have? – none and alot, and, Was that enough support? - Not at all and always.

9. AW kindly suggested engaging with members of the prostate cancer support group to help to pilot the diary. CP and AW will be in contact via email to arrange this.
10. CP highlighted that Mr Nabi (Consultant Urologist) would be willing to join the steering group for this research. The group is excited about this further collaboration. CP will engage with Mr Nabi to finalise this.

Next meeting date: 3 months after recruitment has begun.

Appendix 4.11 Electronic Behavioural Diary Pilot Results

Phase 1 – Colleagues and acquaintances			
Gender (age)	Duration of pilot	Pilot feedback issues	Researcher action
Pilot number 1: Female (32 years old)	1 week	1) The individual was unable to complete the diary data collection because of a limited time period to respond to the audio alarm. The audio alarm was set to 3 minutes. If the participant did not respond to the alarm within the 3 minutes, they could not provide their data entry. This time window was not long enough, given the distraction and activities of daily life.	The time period for the audio alarm reminder was increase for future pilots.
		2) The Access data base did not open the missed entries for the pilot participant, and did not provide data on the usage of the snooze function.	The software developer of Pocket Interview was informed of the problem with the Access database. The problem was fixed, and a newer version of the software was up-dated to prevent this problem happening in the future.
Pilot 2: Female (52 years of age)	2 weeks	1) Missed end of day entries because of limited alarm window, (was set within the same parameters as pilot 1, 3 minutes)	This time period for the audio reminders was extended for future pilots. This was based on the feedback from pilot 1 and 2. The audio alarm was programmed to 30 seconds, every 10 minutes, for 1 hour. This was the maximum alarm capacity of the diary, due to limitations in the software. The audio alarm reminders were incorporated into the working version of the SOP.
		2) This participant was not clear on the term 'fatalistic'.	This comment was reflected upon, within the context of future pilot feedback.
Pilot 3: Female (29 years of age)	2 weeks	1) If there was a missed entry at 'end of day' data entry, the participant was prompted to complete the 'end of day entry' the next morning.	The software programmer corrected this problem by recoding the software programme. Aiming to ensure that if an entry was missed at end of day, the participant did not have an opportunity to complete this the next morning. An up-dated version of the software correcting this problem was the working version for future pilots. The latest version of the software to piloted to check that this particular problem was corrected by the programmer.
Pilot 4: Male (30 years of age)	2 weeks	No problems reported about alarm duration, or issues about completing the end of day entry the following morning.	
Pilot 5: Female (51 years of age)	3 weeks	1) The user was able to exist the Pocket Interview software on the diary, altogether. This was done by tapping a small Windows icon at the top of the PDA screen.	1) Ensuring that the full-screen option is selected within PDA systems, will prevents participants being able to existing the Pocket Interview software.

		2) Qualitative text entries in the diary data was missing, because the pilot participant did not tap first into the white text box. Resulting in missing data because the cursor was not in the white box. This was despite the users tapping the letters to form words.	This maximised the Pocket Interview display on the screen, and as a result the small Windows icon is no longer visible. This was incorporated into the working version of the SOP. 2) The programmer improved the software so that the cursor automatically starts in the box without the user having to tap in this first. This will prevent future problems with missing qualitative text in the future. The Pocket Interview software was up-dated and was the working version for future pilots
Pilot 6: Female (62 years of age)	4 weeks	No problems reported with the qualitative text of any additional software problems.	
Pilot 7: Female (26 years of age)	4 weeks	1) Problems with the end of day self-care questions. The start of the question was half way down the screen, and reports problems with having to scroll to the top of the screen to read the question.	1) The programmer improved the software, so that all of the questions are displayed first at the top of each the screen. This software was up-dated and was the working version for future pilots.
Pilot 8: Male (59 years of age)	4 weeks	No problems reported. The start of the diary questions were displayed at the top of the PDA screen.	
Pilot 9: Male (60 years of age)	4 weeks	1) The researcher also identified that dates for the data entries were recorded incorrectly. Randomly changing the date and month around.	1) The programmer corrected this problem, which enabled the dates for the data points to be correctly formatted for date, month, and year. This software was up-dated to correct this error, and was the working version for future pilots.
Pilot 10: Male (36 years of age)	4 weeks	No problems, questions understandable and easy to complete. The date formatting was correctly displayed for the individual data points.	
Pilot 11: Female (86 years old)	4 weeks	1) Initially found navigating around the screen difficult for the end of day self-care, although managed to complete the data entry. No software problems were reported.	1) The 'Users guide to the behavioural diary' was modified to clearly identify how to navigate around the screen.

Phase 2 – Men with prostate cancer			
Gender (age)	Duration of pilot	Pilot feedback	Researcher action
Pilot number 1: Male (56 years old)	1 week	1) The system crashed, because the user 'unsnoozed' an 'unsnoozed' diary. This was a technical problem with the software. 2) The user reported that he felt that the coping question was slightly ambiguous, 'it asks which statement best describes how you have coped…' It is unclear to the patient, whether they rate one of the statements, or provide ratings for each statement. 3) The pilot participant had no problems with charging the PDA battery, or dexterity problems in completing the diary.	The programmer up-dated the software to correct the problem. The researcher re-piloted the newer version of the software with herself. From the researchers' pilot, the newer version prevented the system from crashing, when 'unsnoozing' an 'unsnoozed' diary. However, a new problem was detected when 'unsnoozing' an 'unsnoozed' diary, in that an extra alarm for a data entry was randomly added to the schedule. The programmer corrected the

		4) The User Guide for the behavioural diary was informative, concise and helpful. 5) The pilot participant felt that the content of the interview schedule was very relevant to his diary experience.	problem of additional alarm in the schedule, and a newer software version was available. The researcher re-piloted the diary using the most up-to-date version, no further problems were detected. The wording of the question was modified to prompt the participant to provide ratings for each of the coping statements.
Pilot 2: Male (62 years of age)	2 weeks	1) No technical problems were reported with the software. 2) The pilot participant had no problems with charging the PDA battery, or dexterity problems in completing the diary. 3) The User Guide for the behavioural diary was informative and useful. Having the researchers contact details, for addition guidance, if required was reassuring to him. 4) He reports that, as a man with prostate cancer he felt that completion of the diary was a positive experience. He felt that men with prostate cancer may find the diary experience therapeutic. 5) The pilot participant felt that the content of the interview schedule was very appropriate to his thoughts of completing the diary.	
Pilot 3: Male (67 years of age)	4 weeks	1) The diary questions were all very relevant to his prostate cancer, however, felt that over the course of the month they became slightly repetitive. 2) The pilot participant had no problems with charging the PDA battery, or dexterity problems in completing the diary. 3) The User Guide for the electronic diary was helpful to look after the researcher explained the diary. It was a useful reminder of how to complete the data entries. 5) The researcher had a problem with transferring the data from the PDA to the Access database.	The software programmer was able to retrieve the data. To prevent future problems, the researcher re-piloted the diary with herself to try and isolate the problem. It was found that special characters for example 'apostrophes' caused the problems with transferring the data. The XML coding was not formatted correctly to handle this data. The programmer up-dated the software to correct this technical problem. The researcher re-piloted the diary, again with herself using the latest version of the software, and rechecked all of the previously reported problems. No problems were detected; therefore the diary was ready for 'live data collection'.

Appendix 4.12 Standard Operating Procedure for Electronic Diary

1. Check the battery status of the PDA. [Start, Settings, System, Power]. Ensure the automatic switching off of the devise is set to preserve battery life [tap turn off the devise if not used in 3 minutes].

2. Locate the battery charging lead and the PDA cover protector.

3. Ensure all the software is appropriately installed onto the PDA. [Client Manager, Install Net Compact Framework 2.0, Install Client]. Should any problems be encountered with client manager [errors], the software developer recommended that a hard reset should be done. It is essential that the software applications are not open on the PDA whilst performing this task.

4. Load the questionnaire on the PDA. [Open Pocket interview program, questionnaire manager, Load, Select FinalPhDquestionnaire Questionnaire, Open, Copy to PDA]

5. Ensure that the schedule is suitable for the participant, in particular, considerations to sleeping patterns. Ensure evenly data points for the schedule i.e. 10am, 4pm, and 10pm. Make the Schedule for the data collection. [Click on the Schedule Manager]. Populate the labels for the schedule, by selecting the FinalPhDquestionnaire [Select questionnaire]. Use the [Individual Prompts] to produce the schedule, 2 standard entries and end of day entry (the 3rd standard entry is prompted automatically before the end of day entry, therefore it is only necessary to populate 2 standard entries) per day for a total duration on one month. Select the date, time and appropriate label 1) diary entry, 2) End of day entry. Use the [repeat function] to populate for the full month.

6. Save the schedule, by participant study number. [Click the save button]. Load the schedule to the PDA [click the Copy Schedule to Pocket PC].

7. Click Initialise on the Pocket PC.

8. Quality check the schedule on the Pocket PC, ensuring that schedule is accurate and present. [System, View Schedule].

9. Change the username on the Pocket PC to the unique study number for the participant. [System, type the username then click Change User].

10. Ensure that the reminders for the diary entry are set [30 secs, 5 reminders and time between the reminders as 10]. Ensure that the full-screen button is 'checked', this is essential as it may allow the use to exit the programme. Tap on the more button and ensure that that [check after snooze for missed is checked].

11. Provide training and support for the participant and provide the 'users guide for the behavioural diary'. [Click on the Demo Mode]. Highlight to the participant, that once the PDA is alarming to prompt data collection, it is too late to activate use the snooze facility. Ensure that the participant is aware to charge the diary every several days. Ensure that the **demo mode is off** when the participant is ready to commence their data collection.

12. Ensure that the participant has the PDA support/training pack to contact the Researcher; the Researcher will contact the participant 24 hours into their data collection, to offer support and answer any questions if necessary.

13. On completion of the data collection. Use the docking system for the PC and the Pocket PC. Rest the Pocket PC in to the Dell Cradle. [click the Data Manager, click copy files from the Pocket PC, enter the encryption password, select new database saving by the unique participant number, and then add data to the participant specific database]. To retrieve the missed entries and the use of the snooze function sync the PDA to the computer [within the Microsoft ActiveSync click explore, my windows, programme files, copy both files mdbpilot1 + zbdpilot1 (e.g. pilot 1 is the name allocated to the PDA) copy files to database folder, open excel and open files as XML format].

14. Check the data has been copied across from the Pocket PC. [Click in the System, List Entries, ensuring that this is now blank].

15. View the data in access. This database is separated by; Missed Entries, Records of snooze function being used, and the 3 questionnaire schedules, Diary Entries, End of Day Entry and Incident Report. The time and date is also recorded when the participant started and stopped each questionnaire sequence.

16. Record in the participants CRF that their behavioural diary data has been successfully and securely downloaded and stored.

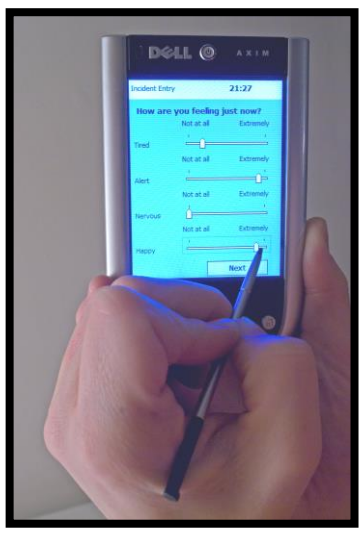
17. Acknowledge many thanks to the participant for their time undertaking the diary data collection.

18. End.

Appendix 4.13 Written Instruction for the Electronic Behavioural Diary

USERS GUIDE TO THE BEHAVIOURAL DIARY

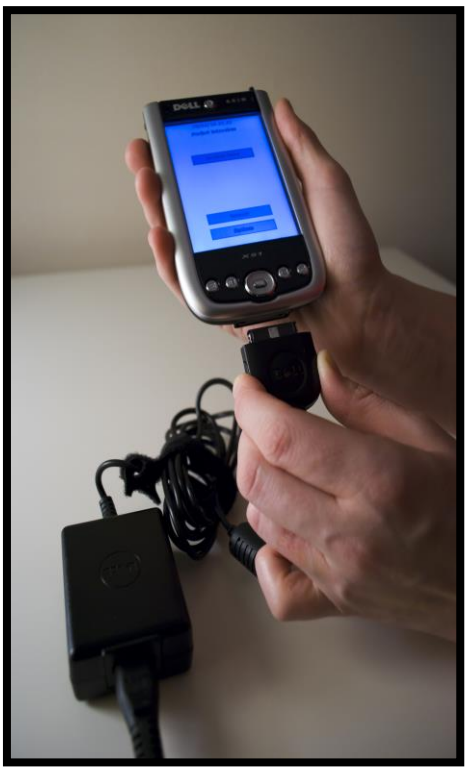
The Behavioural Diary



The diary will sound an alarm at certain intervals throughout the day based on your own preference and guided by the researcher. When the diary makes a sound alarm, this means a diary entry is due for you to complete. If you do not fill in an entry within a short time then the diary will sound again. This will continue for 60 minutes. The diary will continue to alarm until you make an entry. If it is inconvenient to make an entry, then you can activate the *"snooze"* function before you know that the diary is due to alarm. This will allow you to delay the diary entry from 5 or 60 minutes. Tap *"snooze"* and select a snooze duration time (5 to 60 minutes), the diary will then after this time, audio prompt you for the entry. The diary will ask you if you are sure that you would like to "snooze" tap "yes" to confirm. If you do not wish to snooze the diary tap "no" and then tap "back" this takes you back to the main menu.

On the main menu there is a systems button, this is for the research team involved in the study. Please **do not** tap "system". In the event of accidently taping the "system" button please tap "cancel".

Charging the Battery



It is necessary to charge the diary battery each day/every second day. To do this, put the plug into the socket ensuring the power supply is on. Gently squeeze the two buttons on the side of the dell connector. Ensure that the Dell logo is face up on the connector; now connect this to the base of the diary still squeezing the buttons until the connector is firmly attached to the base of the diary. The picture above will give you some guidance. The power button "on/off" button should now have a light on, this means that the battery is successfully charging. When the diary battery is fully charged this light should be "green".

Completing the Diary

When completing the diary questions, don't think over you answers for too long. Please remember that there are no right or wrong answers.

Recording a diary entry

- Remove the stylus (the pointer) from the diary, by lifting it out of the back right hand corner.

- Tap *"Diary Entry"* on the screen with the stylus (pointer).
- The screens that follow will ask you questions. To answer these tap the stylus on the sliding scale or tap the appropriate box to provide your answer to the question.
- When you have completed a screen of questions tap *"Next"*.
- Follow the same procedure for the next 14 screens.
- Once this is done, tap *"Finish"*.
- The diary will then return to the main menu.
- You have successfully completed the diary entry. Thank you and Well Done.

You will repeat this 3 times during the day. At the end of the day, your last diary entry (3rd entry) will be slightly longer that the 2 previous diary entries. There are a few more questions to answer for the 3rd diary entry. Follow the same procedure as before when making the diary entry, tap your answer to the question, then tap "next", continue to follow this procedure, when you have answered all the questions tap "finish". The diary will return to the main menu. Well done.

Recording an incident

You can record an incident/distressing experience at any time throughout the day. A distressing experience can be anything related to your prostate cancer. Again, there are no right or wrong answers, so please tell us as much as you can about the distressing experiences/incidents that you encounter. If you record an incident/distressing experience after a regular diary entry you will be asked similar questions but these relate specifically to the incident.

- Tap *"incident entry"* and follow the same procedure as before when you made your diary entry.
- On the fourth screen you can enter details of the incident. To do this, first tap anywhere in the "white box", this will make the cursor flash in the white box ready for your entry. You should now see cursor (small vertical black line flash on and off) in the box. Once you see this, you are now ready to tap your details of your experience. To do this, use the small keyboard at the bottom of the screen. Tap each letter to spell out words. Once you have finished describing your experience, tap "next". Continue answering the questions as before, when you are at the end of the entry tap "finish" this will take you back to the main menu.

- You have successfully completed the incident Entry. Again thank you and well done.

Pointers/Tips

Typing words - Use the key board to tap the letters to spell words. You should see the letters that you are typing on the screen.

Navigating/changing the diary screen view - You will have to change the view on the screen to read the questions on the diary (only at the end of day entry).

If you have any questions or are experiencing difficulties completing the diary. Please contact **Catherine Paterson**: **Work number: 01382 388645**; E**mail:** c.x.paterson@dundee.ac.uk**. Thank you.**

Appendix 4.14 PDA Diary Schedule

STANDARD ENTRY (COMPLETED 3 TIMES PER DAY, TOTAL OF 1 MONTH)

Q1 How are you feeling just now? (MOOD)

Alert Not at all_____Extremely
Tired Not at all_____Extremely
Happy Not at all_____Extremely
Nervous Not at all_____Extremely
Frustrated Not at all_____Extremely
Sad Not at all_____Extremely
Energetic Not at all_____Extremely
Angry Not at all_____Extremely
Stressed Not at all_____Extremely

Q2 Please rate each of the following statements which describes how you have coped in the last few hours with your self-care tasks? (COPING)

I tried to keep a positive attitude
Not at all_____Always
I felt like giving up
Not at all_____Always
I felt problems with my health prevent me from planning ahead
Not at all_____Always
I felt that nothing I can do will make a difference
Not at all_____Always
I tried not to think about it
Not at all_____Always

Q3 Think about the last few hours.

I can always manage to complete self-care activities that are difficult for me.
Not at all_____Always

I am confident in carrying out my self-care activities.
Not at all_____Always

Q4. Think about self-care activity in the past few hours.

a) How demanding has self-care been for you?

Demanding
Not at all_____Extremely

b) How much control have you had over your self-care?

Control
Not at all_____Completely

Q5 Have you sought out support in the last few hours?

No ☐ Yes ☐

Q6 How much support have you had in the last few hours? (RECEIVED SUPPORT)

Financial	None_____Alot
Emotional	None_____Alot
Informational	None_____Alot
Practical	None_____Alot

Q7 Do you have enough available support from people around you? (PERCEIVED SUPPORT)

Financial	Not at all_____Alot
Emotional	Not at all_____Alot
Information	Not at all_____Alot
Practical	Not at all_____Alot

END OF STANDARD ENTRY

END OF DAY ENTRY (IMMEDIATELY FOLLOWING 3RD STANDARD ENTRY)

Q1 What types of self-care have you used today to help with your water works (urine)?

None ☐ (if ticked Q2)

Took medication ☐
Found out information ☐
Increased fluid intake ☐
Used pads ☐
Used catheters ☐
Used urine sheaths ☐
Pelvic floor exercises ☐
Avoided heavy lifting ☐
Kept a toileting diary ☐
Avoided caffeine based ☐
Drinks ☐
Shared my feelings ☐

Other ☐

Please describe text box.

Generally, did your self-care actions relieve the problem?

Not at all_____Completely

Q2 What types of self-care have you used today to help with your bowels?

None ☐ (if ticked Q3)

Took medication ☐
Increased fluid intake ☐
Changed diet ☐
Used pads ☐
Did pelvic floor exercises ☐
Kept a toileting diary ☐
Found out information ☐
Comfort (hot water bottle) ☐
Shared my feelings ☐
Other ☐

Please describe text box.

Generally, did your self-care actions relieve the problem?

Not at all_____Completely

Q3 What types of self-care have you used today to help with your sexual function?

None ☐ (if ticked Q4)

Took Medication ☐
Found out information ☐
Tried to lose weight (if overweight) ☐
Limited alcohol intake ☐
Stopped smoking (if smoke) ☐
Used a penis pump ☐
Took exercise ☐
Found ways to reduce stress ☐
Shared my feelings ☐

Other ☐

Please describe

Generally, did your self-care actions relieve the problem?

Not at all_____Completely

Q4 Overall today I feel that:

I can always manage to complete self-care activities that are difficult for me.

Not at all_____Always

I am confident in carrying out my self-care activities.

Not at all_____Always

Q5 To what extent have you experienced the following symptoms today? (EORTC)

Blood in urine Not at all_____Always
Constipation Not at all_____Always
Diarrhoea Not at all_____Always
Nausea Not at all_____Always
Pain Not at all_____Always
Tiredness Not at all_____Always
Unable to sleep Not at all_____Always
Urgency to pass urine Not at all_____Always
Urinate frequently (day) Not at all_____Always
Urinate frequently (night) Not at all_____Always
Vomiting Not at all_____Always
Impotence Not at all_____Always

Q6 Did you use any other self-care activities (not already mentioned) to help alleviate your symptoms/problems today?

Yes ☐ (if yes Q7) No (if no Q8) ☐

Q7 Please describe the problem/symptom for which you carried out your self-care?

Problem/symptom
Text box

Please describe the self-care tasks
Text Box

Generally, did your self-care actions relieve this problem?

Not at all_____Completely

Q8 What was your most demanding self-care task that you had to do today?

Please describe.

Q9 How satisfied were you with your support today? (SATISFIED SUPPORT)

Financial Not at all_____Extremely
Emotional Not at all_____Extremely
Informational Not at all_____Extremely
Practical Not at all_____Extremely

Q10 Were you able to discuss your thoughts and feelings today?

Not at all_____Always

Did you want to discuss your thoughts and feelings today?

Not at all_____Always

Q11 Has there been any change to your treatment/medication today?

Yes ☐ (If yes please describe) No ☐

Please describe what the treatment change was.

Q12 How would you rate your quality of life today? (EORTC)

Very poor_____Excellent

END OF 'END OF DAY ENTRY'

EVENT CONTINGENT ('INCIDENT ENTRY' CAN BE COMPLETED AT ANY TIME WITHIN THE 1 MONTH PERIOD)

Q1 How are you feeling just now? (MOOD)

Alert Not at all_____Extremely
Tired Not at all_____Extremely
Happy Not at all_____Extremely
Nervous Not at all_____Extremely
Frustrated Not at all_____Extremely
Sad Not at all_____Extremely
Energetic Not at all_____Extremely
Angry Not at all_____Extremely
Stressed Not at all_____Extremely

Q2 Please describe your experience that was very demanding for you?

What happened

Free text

Q3 Please rate the following statements which describes how you have coped with this experience? (MAC Scale)

I tried to keep a positive attitude
Not at all_____Always
I felt like giving up
Not at all_____Always
I felt problems with my health prevent me from planning ahead
Not at all_____Always
I felt that nothing I can do will make a difference
Not at all_____Always
I tried not to think about it
Not at all_____Always

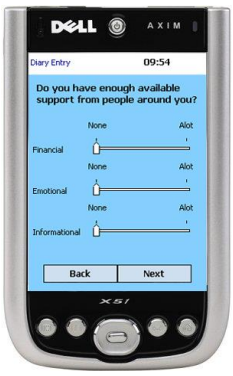
Q4 Did you seek support to help with this experience?

No ☐ Yes ☐

Q5 Did you have enough support available from people around you? (PERCEIVED SUPPORT)

Not at all_____Alot
Was that enough support?
Not at all_____Always

Thank you *END OF INCIDENT ENTRY*



Appendix 4.15 Sampling Framework: Reviewed Studies using the Berlin Social Support Scales (BSSS, Schulz and Schwarzer, 2003).

Authors	Item number	Sample	Time point social support assessed (trajectory)	Mean and SD
Schwarzer *et al* (2006)	Received emotional support 6 items Cronbach's alpha= 0.87 T1 = 0.83 T2 = 0.79 T3	N=117 (73 men and 44 women) mixed cancer sites, age 62.7, SD 10.4	T1 before cancer surgery T2 I month T3 12 months	T1 3.81 SD 0.30 T2 3.77 SD 0.39 T3 3.73 SD 0.38 Scored 1, 2, 3, 4 Total maximum mean score 4
Scholz *et al* (2008)	Received social support 2 items for 2 subscales (emotional and instrumental) support. 4 items in total Cronbach's alpha reported = 0.67	All men under went laparoscopic radical prostatectomy for PC N=77	Assessed 2 weeks after surgery	2.66 SD 0.47 Scored 0, 1, 2, 3, total score min 0 max 12 Total maximum mean score 3
Boehmer et al (2007)	Received social support 10 items (6 items emotional, 3 items instrumental, 1 item satisfaction) Cronbach's alpha= 0.89	N=240 1 month after surgery for varying malignant sites and gender (58% men, 42% women) 63 years SD 10.3 (range 22-86)	1 month after surgery	3.80 SD 0.37 range 2.0-4.0 Scored 1, 2, 3, 4, total score min 10, max 40 Total maximum mean score 4
Luszcynska et al (2005)	Received social support (emotional, instrumental and informational) Total item 10 (items not broken down) Cronbach's alpha= 0.87	N=255 with varying site of malignant tumours, 61.9 % men, 62.8 years SD 10,9 (range 24-86)	1 month after surgery	3.72 SD 0.38 Scored 1 – 4, total score min 10, max 40 Total maximum mean score 4
Luszcynska et al (2007)	Received social support emotional support (6 items) Cronbach's alpha= 0.85	N= 480 cancer patients recruited 3 days before surgery , N=294 I month after surgery, N=233 patients 6 months after surgery Mixed cancer sites, 60.2% men, age 62 SD 11.8	T1 3 days before surgery T2 I month after T3 6 months	Men T1 3.89 SD 0.26 n=108 T2 3.90 SD 0.21 T3 3.89 SD 0.27 Women T1 3.85 SD 0.28 T2 3.79 SD 0.38 T3 3.65 SD 0.42 Both T1 3.87 SD 0.27 T2 3.89 SD 0.29 T3 3.80 SD 0.35 Scored 1 – 4, total score min 6, max 24, Total maximum mean score 4

Appendix 5.1 Associations with Demographic and Clinical Variables with the Questionnaire Survey Data

Categorical variable	Anxiety (square root)	Depression $_{(log)}$	Global quality of life $_{(square\ root)}$
Demographic:			
Socio-economic	F(4, 63)=2.341, p=.065	F(4, 63)=.574, p=.682	F(4, 62)=1.204, p=.318
Education level	F(2, 65)=1.064, p=.315	F(2, 65)=.270, p=.515	F(2, 64)= 1.477, p=.236
Clinical variables:			
Cancer staging	F(2, 65)=.594, p=.555	F(2, 65)=2.741,p=.183	F(2, 64)=2.742, p=.072
Treatments	F(5, 61)=1.371, p=.241	F(5, 62)=1.429,p=.227	F(5, 61)=1.367, p=.249
Gleason score	F(3, 64)=.644, p=.590	F(3, 64)=.258, p=.856	F(3, 63)=.682, p=.566

Categorical variable	Self-efficacy	Perceived Stress	Social support
Demographic:			
Socio-economic	F(4, 64)=.516, p=.673	F(4, 63)=1.799, p=.140	Perceived: F(4, 63)=1.499, p=.213 Received: F(4, 63)=.638, p=.638 Satisfaction: F(4, 63)=1.069, p=.308
Education level	F(2, 65)=.328, p=.721	F(2, 65)=.862, p=.427	Perceived: F(2, 65)= .617, p=.534 Received: F(2, 64)=.783, p=.461 Satisfaction: F(2, 63)=.717, p=.492
Clinical variables:			
Cancer staging	F(2, 65)=2.123, p=.128	F(2, 65)=.021, p=.979	Perceived: F(2, 65)=1.534, p=.122 Received: F(2, 64)=.207, p=.814 Satisfaction: F(2, 63)=.409, p=.666
Treatments	F(5, 62)=1.523, p=.196	F(5, 62)=1.434, p=.225	Perceived: F(5, 62)=.851, p=.519 Received: F(5, 61)=.623, p=.683 Satisfaction: F(5, 60)=.231, p=.948
Gleason score	F(3, 64)=.526, p=.673	F(3, 64)=.317, p=.813	Perceived: F(3, 64)=.1.287, p=.286 Received: F(3, 63)=.906, p=.443 Satisfaction: F(3, 62)=.746, p=.529

Appendix 6.1 Standard Operating Procedure: Analysis Guidance Points: N-of-1 Diary Data

Summary definition points:

Lag: Time period between two observations.

Autocorrelation: Correlations among sequential scores at different lags.

Autocorrelation function: The pattern of autocorrelations in a series at numerous lags.

Partial autocorrelation function: The pattern of partial autocorrelations in a series at numerous lags after partialling out the effects of autocorrelations at intervening lags. In summary, this provides a "clearer" picture of the presence of autocorrelation in a time series.

Moderation: A moderator variable alters the strength of the relationship between a predictor variable and dependent variable.

Mediator: A mediator variable explains the causal relationship between the predictor variable and dependent variable.

Linearity: Is a way of describing the relationship between variables. The mean values of the outcome and mean values of the predictor variable(s) are plotted against a straight line.

Independence of the errors (no serial correlation): is an assumption in regression analysis; this means that there should be no correlation for any 2 residuals. Residuals should all be independent. This assumption can be checked with the Durbin-Watson test and by checking the autocorrelations and partial autocorrelation functions of the residuals.

Homoscedasticity (constant variance): is a requirement that should be met in regression analysis. This term means that the spread of the residuals should be fairly constant in the model.

Multicollinearity: this is a term used to describe that there should be no perfect linear relationship between two or more predictors in the regression analysis. Multicollinearity indicates that the predictor variables should not be correlated too highly, that is to say, correlations above R=<0.90.

(Tabachnick and Fidell, 2007, Field, 2005)

Steps in SPSS: Standard entry analysis to test for main, moderation, and mediation effects in relation to the 3rd research question.

Section A:

1) Screen the data for normality, outliners and missing data.

2) Plot a time series of the variables to explore and get a feel of the data. This is performed in SPSS →Time Series, Sequence Charts. Do a visual check for any trends in the data over time for each variable (Tabachnick and Fidell, 2007).

3) Check autocorrelation/partial correlation functions. Autocorrelation is defined as the correlations among sequential scores at different lags (lag is defined as the time periods between 2 observations). For example, a lag of 1, the pair at time 1 and time 2, the pair at time 3 and time 4, and so on. A lag of 2 autocorrelation coefficient is similar

to correlations between the pairs of scores at 2 time points apart; for example, the pair at time point 1, and time point 3, and the pair at time point 2 and time point 4, and so on. Autocorrelations Function (ACF) is the pattern of autocorrelations in a time series at numerous lags. Partial autocorrelation function (PACF) is the pattern of partial autocorrelations in a series at numerous lags after removing the effects of autocorrelations at intervening lags. The autocorrelation function tells researchers about the structure of serial dependence in each data series (Cromwell et al., 1994).

- This is performed in SPSS → Autocorrelations → check the residuals from the regression model. Apply this question whilst doing a visual check of the output, "what do the lags tell us about the data series?" It is good practice to run ACF and PACF for unaltered variables and transformed/standardised variables, as a quality check.

4) If autocorrelation is detected in the series it is necessary to pre-whiten the variables, this is an essential part of multivariate time series analysis to reduce random noise. Pre-whitening means generating a series that has approximately the same level of power at all frequencies or white noise (white light has equal contributions at different frequencies and therefore, it is termed pre-whitening, Tabachnick and Fidell, 2007).

   a) First the researcher should generate new lagged variables [SPSS, Transform, Create time series, move the DV into the variable view, then select lag variable from the drop down window, then click continue].

   b) Now the researcher has created a pre-whitened variable in linear regression. It is necessary to regress the variable on the lagged variable and store the standardised residual, this is our new pre-whitened variable (Cromwell et al., 1994). To do this [analyse, regression, linear, move the variable to dependant viewer and move the lagged variable into the independent variable viewer. In "save" ensure; "save the standardised residuals" is checked, in the main regression window click "ok"]. Change the variable name and variable label in the viewer for the new pre-whitened variable.

   c) Now check that the ACF and PCF for the pre-whitened variable. Do a quality check to establish if the pre-whitening procedure has worked on the variable.

5) If pre-whitening procedure on the variable has worked effectively, it is appropriate to run the regression.

6) For data (particularly DV), where appropriate; undertake appropriate transformations to meet the assumption of normally (see Tabachnick and Fidell, 2007).

7) A correlation analysis between the independent and dependent variables should be performed to check for significant correlations; which will subsequently inform the moderation/mediation analysis to address the third research question.

8) Standardise the IV and moderator variables; and it is worthwhile re-checking the time series plot using the standardised variables. STANDARDISING: The first step in testing moderation is standardising the continuous variables. The rationale for this is because the predictor variables and moderator variables are generally highly correlated when the interaction term is created. Standardisation of the variables reduces the problem of multicollinearity (Frazier et al., 2004). It is appropriate to standardise the independent variable and the moderator variable.

    1. SPSS →Analyse → Descriptive statistics → Descriptive →Select the variable →Click Standard values as variables (Field, 2005)

9) Testing moderation effects: CREATING PRODUCT TERMS using pre-whitened (if necessary) one multiplies together the predictor and moderator variables using the standardised variables (Frazier et al., 2004). This can be done in compute variables.

10) STRUCTURING THE EQUATION FOR MODERATION: Enter the variables into the regression equation through specified blocks/steps. Step 1: Enter the independent, moderator and dependent variable, Step 2: enter the integration term (independent variable X moderator variable).

11) To establish whether testing moderation/mediation is appropriate using ordinary least squares regression. There are 4 principle assumptions that must be checked, a) **linearity** of the relationship between dependent and independent variables, b) **independence** of the errors (no serial correlation), c) **homoscedasticity** (constant variance) of the errors, d) **normality**.

12) To answer this question the researcher must examine the model's residuals (SPSS ®, 2004).

13) **Run the regression.** In SPSS → Analyse → Regression → Linear.

    a) Click statistics → select Estimates, Confidence intervals, Model fit, R square change, descriptive, Part and partial correlations, Collinearity diagnostics, Durbin-Watson, Casewise diagnostics and set outliners to 2 standard deviations in the residuals group → Click continue.

    b) Click plots → select normal probability plot, and plot *ZRESID (y axis) against *ZPRED (x-axis); this will check the assumptions of random errors and heteroscedasticity.

    c) Click Save → select Predicted values Unstandardized, Standardised, Adjusted → Distances Mahalanobis, Cook's and Leverage values → Residuals select; unstandardized Standardised, deleted and studentized residuals → click continue.

    d) Click OK → run the regression.

14) **Check the autocorrelation of the residuals.** Look the results of the Durbin-Watson statistic, which is a measure of the first-order (lag 1) autocorrelation of the residuals. This provides a check of the assumption of the uncorrelated residuals. The values range from 0 to 4, values near 2 indicated non-autocorrelation, values towards 0 indicates positive autocorrelation and values towards 4 indicates negative autocorrelation (Tabachnick and Fidell, 2007; SPSS ®, 2004). It may also be necessary to look up the "Durbin-Watson" significance tables. It is also appropriate to plot the autocorrelation/partial correlation functions of the residuals.

15) **From the output:** look at the "Correlation" matrix for multicollinearity, that is checking predictors are not too highly correlated with each other, R>0.90.

    a) The fit of the regression model can be checked using "Model Summary" and "ANOVA" from the tables in SPSS. Looking at the R^2 will identify the proportion of variance explained by the model. ANOVA will evaluate whether the model is a good overall fit of the data ($P<0.05$).

    b) Check the Durbin-Watson test to check that the assumption that the errors (residuals) are independent (it is likely to be met if the value is close to 2).

    c) The individual contributions of the variables to the regression model can be found in the "Coefficients" the beta values and their level of significance ($P<0.05$).

d) To further check of no multicollinearity, use the variance inflation factor (VIF) values from the coefficients tables. If these values are less than 10 this indicates that generally this assumption has been met.

e) Outliners that might be influencing the model can be checked by the "Mahalanobis and Cooks distance" values. For interpretation of the Cook's distance generally values greater than 1 maybe cause for concern, and for the Mahalanobis a crude check is to look for values above 15 in samples smaller than 100.

f) Check the assumptions of the following: normality, linearity and Homoscedasticity of residuals. This is done by a visual check of the P-P plot and the histograms. If the histogram and the P-P plot are normal in distribution, then these assumptions are likely to be met.

16) INTERPRETING THE RESULTS: First interpreting the results of the effects of the predictor and moderator variables, second testing the significance of the moderator effect.

17) If it was necessary to pre-whiten the data look at the relationships in the raw data in addition to the pre-whitened data. This is done in SPSS →Correlations. Are there any significant relationships? If relationships are present in the pre-whitened variables on the not in the standard variables try and establish why.

Section B: Testing from mediation

1) To test for mediation requires the estimation of three regression equations: a) regressing the independent variable on the dependent variable b) regressing the independent variable on the mediator c) then regressing both the independent variable and the mediator variable on the dependent variable (Baron and Kenny, 1986, Frazier et al, 2004).
2) To establish mediation, the following conditions must hold 1) the independent variable must affect the mediator in the first regression, 2) the independent variable must affect the dependent variable, 3) the mediator must affect the dependent variable in the third regression. If mediation is present then the effect of the independent variable on the dependent variable in the third equation should be less in the third equation than the second (Baron and Kenny, 1986; Frazier et al, 2004).

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Appendix 6.2 Mr D's Additional Self-Management Behaviours

Date	*Symptom*	*Self-management behaviour*	*Relief 0-100*
31/01/2011	Swollen ankles	Went for a walk	14
01/02/2011	Swollen ankles	Go for walks, elevate feet when sitting, took furosamide pills	0
02/02/2011	Swollen ankles	Go for walks, elevate feet when sitting, took furosamide pills, had a foot massage	22
03/02/2011	Swollen ankles	Go for walks, elevate feet when sitting, took furosamide pills	8
04/02/2011	Swollen ankles. Pus oozing out from wound in stomach region	Took furosamide pill, walking, dressed wound	37
05/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pills, walking, dressed wound	23
06/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pills, walking, dressed wound twice today	22
07/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pills, walking, dressed wound twice today	8
08/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pills, walking, dressed wound twice today	17
09/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pill, took exercise and elevated legs when sitting. Went to local outpatient department where a nurse examined and dressed wound	48
10/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pill, took exercise and elevated legs when sitting. Wound was redressed at local outpatients dept.	15
11/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pill, took exercise and elevated legs when sitting. Went to Ninewells to have a bag attached to drain wound to collect discharge after my practice doctors contacted the consultant. Also shown how to drain and change bag.	46
12/02/2011	Swollen ankles. Leakage from drain wound	Took furosamide pill, took exercise and elevated legs when sitting. Checking bag on drain wound was secure and emptying bag when needed.	46
13/02/2011	Leakage of drain wound	Replaced bag with a new one	100
14/02/2011	Leakage from drain wound	Bag attached to drain wound to collect discharge	100

15/02/2011	Discharge from drain wound	Making sure bag at drain site is not leaking and emptying bag when necessary	100
16/02/2011	Discharge from drain wound	Making sure bag at drain site is not leaking and emptying bag when necessary	100
17/02/2011	Discharge from drain wound	Making sure bag at drain site is not leaking and emptying bag when necessary	100
18/02/2011	Discharge from drain wound	Making sure bag at drain site is not leaking and emptying bag when necessary	100
19/02/2011	Discharge from drain wound	Changing drain wound bag	100
20/02/2011	Discharge from drain wound	Emptying bag when necessary	100
21/02/2011	Discharge from drain wound	Very little discharge from wound. Replaced bag with dressing	81
22/02/2011	Discharge from drain wound	Change dressing when necessary	100
23/02/2011	Slight discharge from drain wound	Change dressing when necessary	88
24/02/2011	Red patch on skin above drain wound. Diagnosed by GP as an infection	Prescribed antibiotics by GP who said if the patch increased in size and there was no improvement in 48 hours I should contact Ninewells	0
25/02/2011	Red patch on skin above drain wound	Taking antibiotics and checking red patch does not increase in size	17
26/02/2011	Red patch on skin above drain wound	Taking antibiotics which seem to be helping	44
27/02/2011	Red patch on skin above drain wound	Taking antibiotics which seem to be effective	51
28/02/2011	Red patch on skin above drain wound	Taking antibiotics which seem to be helping	67
29/02/2011	Red patch on skin above drain wound	Taking antibiotic which seem to be clearing up the infection	76

Appendix 6.3 Preliminary Analysis of 10 Single-Case Studies (Mr B to Mr K)

Case report Mr B

Mr B is 61 years old, married man who was diagnosed with localised prostate cancer and was monitored through active surveillance. A number of autocorrelations were found for positive coping (at a lag 1), negative coping (at a lag of 3), self-management demand (at a lag of 2), negative affect (at a lag of 2), positive affect (at a lag of 1) and perceived social support (at a lag of 1). Pre-whitening successfully removed these autocorrelations. No other variables displayed autocorrelation.

Positive affect $_{(PreW\ lag\ 1)}$ displayed positive kurtosis (P<0.001) and the K-M was significant (83) = 0.103, P=0.031. A constant of 35 was added to the transformation (the largest of the negative values was -34.1) because without a constant the negative data points would have been lost because the square roots of negative numbers cannot be calculated. A SQRT transformation (+ 35) improved normality (K-M [83] = 0.083, P=0.200) for positive affect $_{(PreW\ lag\ 1)}$. Transformations (Tabachnick and Fidell, 2007) were applied to positive coping $_{(PreW\ lag\ 1)}$, negative coping $_{(PreW\ lag\ 3)}$, and self-management demand $_{(PreW\ lag\ 2)}$, but did not achieve normality, and were left untransformed.

Descriptive statistics of study variables – Mr B

Mr B reported moderate (71.2, SD 22.6) perceived social support and very little received social support, see table 1. He was also dissatisfied with his social support, see table 2. These data suggest that he was not able to discuss his thoughts and feelings and he did not want to. Mr B did not complete any incident reports.

Table 1 Mr B: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-care demand	84	0	6	0.27	0.9
Self-care control	84	62	100	99.5	4.1
Positive coping	84	80	100	99.3	3.5
Negative coping	84	1	28.2	23.5	5.9
Negative affect	84	0	16.6	0.5	2.0
Positive affect	84	17.3	100	55.1	14.3
Self-care self-efficacy	84	99.5	100	99.9	0.1
Received social support	84	0	26.5	0.6	3.0
Perceived social support	84	38.5	100	71.2	22.6

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 2 Mr B: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	29	23.7	100	61.1	18.5
Were you able to discuss your thoughts and feelings today?	29	0	4	0.3	0.9
Did you want to discuss your feelings today?	29	0	3	0.3	0.7
Overall, self-care self-efficacy	29	100.0	100	100.0	0.0

Quality of life	29	69	100	97.8	7.9

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Descriptive statistics for Mr B's symptoms are presented in table 3. The frequently experienced symptoms were urinary urgency and frequency.

Table 3 Mr B: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	29	0	43	4.2	12.0
Blood in the urine	29	0	3	0.3	0.8
Diarrhoea	29	0	5	0.6	1.4
Impotence	29	0	4	0.3	0.9
Nausea	29	0	7	0.5	1.4
Pain	29	0	5	0.6	1.4
Tiredness	29	0	31	3.6	8.9
Unable to sleep	29	0	25	2.2	5.9
Urgency to pass urine	29	40	57	51.0	4.0
Urinate frequently during the day	29	38	56	49.7	3.8
Urinate frequently at night	29	20	52	44.1	9.7
Vomiting	29	0	5	0.7	1.6

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom.

A correlation analysis was undertaken between all the variables (including unaltered and altered variables) see table 4.

Table 4 Pearson's product moment correlation coefficients between all variables (unaltered and altered variables) for Mr B

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1) Positive coping	1															
2) Positive coping $_{\text{PreW lag 1}}$	0.945**	1														
3) Negative coping	-0.050	-0.117	1													
4) Negative coping $_{\text{PreW lag 3}}$	-0.007	-0.046	0.946**	1												
5) Demand	0.054	0.130	-0.522**	-0.319**	1											
6) Demand $_{\text{PreW lag 2}}$	0.256*	0.309**	-0.406**	-0.245*	0 .939**	1										
7) Control	-0.021	-0.015	-0.029	-0.014	0.031	0.019	1									
8) Negative affect	-0.453**	-0.433**	-0.236*	-0.201	0.351**	0.264**	0.030	1								
9) Negative affect $_{\text{PreW lag 2}}$	-0.382**	-0.360**	-0.089	0.035	0.202	0.158	0.018	0.910**	1							
10) Positive affect	0 .012	-0.002	-0.022	0.050	0.120	0.106	0.008	-0.126	-0.190	1						
11) Positive affect $_{\text{PreW lag 1}}$	-0.015	-0.024	0.036	0.021	0.056	0.070	0.029	-0.116	-0.169	0.966**	1					
12) SQRT positive affect $_{\text{PreW lag 1}}$	-0.008	-0.013	0.022	0.013	0.069	0.101	0.018	-0.136	-0.175	0.939**	0.974**	1				
13) Self-efficacy	-0.021	-0.015	0.422**	-	-0.082	-0.022	-0.012	-0.102	-0.103	0.039	-0.013	-0.024	1			
14) Received social support	0.041	0.161	-0.599**	-0.562**	0.458	0.767**	0.023	0.147	0.199	0.201	0.029	-0.042	-0.059	1		
15) Perceived social support	-0.247*	-0.178	-0.090	-0.038	-0.026	-0.112	0.103	0.178	0.084	0.254*	0.258*	0.173	-0.141	0.023	1	
16) Perceived social support $_{\text{PreW lag}}$	-0.225*	-0.187	-0.038	-0.028	-0.024	-0.082	0.063	0.110	0.043	0.404**	0.376**	0.293**	-0.088	0.007	0.896*	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr C

Mr C was 51 year old, married gentleman who was diagnosed with localised prostate cancer and treated by laparoscopic radical prostatectomy (LRP). A number of significant autocorrelations were found at a lag of 1 for the following variables: self-management demand, negative affect, self-efficacy, received and perceived social support. The pre-whitening procedure was applied to each of these variables, and successfully removed the presence of autocorrelation.

Self-management demand $_{(Pre\text{-}W\ lag\ 1)}$ displayed positive skewness and the K-S was significant D (80) = 0.506, p<0.001. A square root transformation (+ constant of 36 [lowest negative number was -35.21]) was successful in reducing the impact of univariate outliner and improved normality, K-S D(79)= 0.077, p=0.200. Negative affect $_{(pre\text{-}W\ lag\ 1)}$ displayed a univariate outliner and a square root transformation (+ constant of 12 [the lowest negative value was -11.64]) effectively reduced the impact of the outliner and improved normality.

Descriptive statistics for Mr C

Mr C reported little received social support and had high perceived social support; with overall satisfaction (see table 5 and 6). He experienced reduced quality of life and experienced a number of symptoms (see table 6 and 7).

Table 5 Mr C: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Positive coping	80	52	100	97.6	9.1
Negative coping	80	8.5	66	36.9	9.7
Self-care demand	80	0	100	32.1	20.5
Self-care control	80	11	100	42.3	20.4
Negative affect	80	0	36.6	6.7	6.6
Positive affect	80	36	100	72.5	16.4
Self-care self-efficacy	80	69.5	100	97.5	5.4
Received social support	80	0	57.7	4	12.9
Perceived social support	80	0	100	97.1	12.9

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 6 Mr C: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	32	77.2	100	97.1	3.6
Were you able to discuss your thoughts and feelings today?	32	0	100	93.6	21.0
Did you want to discuss your feelings today?	32	0	100	95.7	18.1
Overall, self-care self-efficacy	32	21.5	100	94.7	14.7
Quality of life	32	34	100	86.5	16.1

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Mr C experienced a range of symptoms (see table 7) and these included: impotence, tiredness, urgency and urinary frequency. Mr C did not experience any bowel dysfunction.

Table 7 Mr C: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	32	0	12	0.94	3.0
Blood in the urine	32	0	0	0	0
Diarrhoea	32	0	0	0	0
Impotence	32	0	100	84.8	17.2
Nausea	32	0	0	0	0
Pain	32	0	20	1.47	4.3
Tiredness	32	0	70	28.9	17.9
Unable to sleep	32	0	41	1.9	7.7
Urgency to pass urine	32	3	100	33.5	25.8
Urinate frequently during the day	32	7	100	42.3	28.3
Urinate frequently at night	32	0	84	25.8	23.4
Vomiting	32	0	0	0	0

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom

Four incident entries were completed (see table 8). Mr C's incident reports were related to urinary dysfunction and rectal pain. He experienced negative affect (23.4, SD 22.9) and reported low perceived social support (45.5, SD 45.4) at the time of his incident entries.

Table 8 Mr C: Incident entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Incident entry variables	N	Minimum	Maximum	Mean	SD
Positive coping	4	41	100	81.5	27.9
Negative coping	4	29.7	57	40.7	11.6
Negative affect	4	0	49	23.4	22.9
Positive affect	4	20.7	70.7	49.2	23.2
Received social support	4	0	100	35.5	46.2
Perceived social support	4	0	100	45.5	45.4

Incident entry date and time:	**Sought support**	**Description of the incident**
01.02.2011 17:16	No	Passed urine when coughing.
02.02.2011 19:24	No	I feel that my bladder control is non-existent at the moment and it is getting extremely frustrating for me now.
05.02.2011 03:59	No	Due to the retracted penis pouch becoming unstuck, as a result of this the bed got very wet and everything needed changing.
26.02.2011 19:34	No	Severe rectal pain came on very suddenly. Tramadol taken for pain and also movicol.

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

The bivariate correlation analysis for Mr C is presented in table 9.

Table 9 Pearson's product moment correlation for all variables for Mr C

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1) Negative coping	1																
2) Positive coping	-0.260*	1															
3) Demand	0.327**	-0.335**	1														
4) Demand $_{\text{pre-W lag 1}}$	0.280**	-0.301***	0.942**	1													
5) SQRT Demand $_{\text{pre-W lag 1}}$	0.0272**	-0.245**	0.902**	0.976**	1												
6) Control	-0.080	-0.056	-0.082	-0.108	-0.151	1											
7) SQRT Control	-0.050	-0.072	-0.033	-0.064	-0.103	0.989**	1										
8) Positive affect	-0.073	0.285*	-0.230*	-0.200	-0.180	-0.149	-0.133	1									
9) Negative affect	0.465**	-0.663**	0.575**	0.465**	0.376**	-0.016	0.015	-0.148	1								
10) Negative affect pre-$_{\text{W lag 1}}$	0.465**	-0.626**	0.502**	0.472**	0.406**	0.018	0.052	-0.182	0.841**	1							
11) SQRT Negative affect $_{\text{pre-W lag 1}}$	0.440**	-0.525**	0.459**	0.430**	0.376**	-0.017	0.013	-0.169	0.761**	0.975**	1						
12) Self-efficacy	-0.248**	0.300**	-0.408**	-0.291**	-0.214	0.014	0.010	0.299**	-0.561**	-0.371**	-0.308**	1					
13) Self-efficacy $_{\text{pre-W lag 1}}$	-0.307**	0.206	-0.384**	-0.344**	-0.301**	0.057	0.048	0.229*	-0.348**	-0.288*	-0.267**	0 .774**	1				
14) Received social support	0.085	-0.173	0.230*	0.197	0.108	0.033	0.017	0.162	0.363**	0.280*	0.167	-0.489**	-0.297**	1			
15) Received social support $_{\text{pre-W lag 1}}$	0.316**	-0.210	0.167	0.118	0.048	-0.008	-0.032	0.166	0.428**	0.287*	0.192	-0.455**	-0.304**	0.959**	1		
16) Perceived social support	-0.104	0.209	-0.102	-0.130	-0.122	-0.131	-0.145	0.218	-0.238**	-0.128	-0.056	0.230*	0.151	-0.273*	-0.188	1	
17) Perceived social support $_{\text{pre-W lag 1}}$	-0.120	0.027	0.006	-0.026	-0.054	-0.122	-0.135	0.171	-0.073	-0.008	0 .040	0.132	0.086	-0.149	-0.134	0.941**	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr D

Mr D was a 59 year old married gentleman, treated by LRP for his localised prostate. A number of significant autocorrelations were found for the following variables: negative coping (at lag of 2), negative effect, received and perceived social support (all at a lag of 1), and positive affect (at a lag of 3). The pre-whitening procedure was applied to each of these variables, and successfully removed the presence of autocorrelation. Pre-whitened negative coping displayed kurtosis $p<0.001$, the K-S statistic significant $D(92)=.119$, $p=0.002$. A constant of 11 was added to the square root transformation (the largest of the negative values was -10.12) and this was effective in improving the normality of this negative coping (Pre-W lag 2).

Descriptive statistics for Mr D

Social support scores were low for perceived and received social support (see table 10); with overall low satisfaction scores, see table 11. Mr D reported reduced quality of life and also experienced a number of symptoms (see table 12).

Table 10 Mr D: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Positive coping	90	99	100	99.9	0.1
Negative coping	90	11	33.5	19.8	4.3
Self-care demand	90	0	32	1.5	4.5
Self-care control	90	80	100	99.7	2.3
Negative affect	90	0	10.2	0.34	1.32
Positive affect	90	15	77.7	50.8	14.1
Self-care self-efficacy	90	97.5	100	99.9	0.3
Received social support	90	4.7	62	13.7	9.2
Perceived social support	90	9	88.7	20.1	14.5

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 11 Mr D: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	31	8.5	48.2	18.8	11.0
Were you able to discuss your thoughts and feelings today?	31	66	100	98.9	6.1
Did you want to discuss your feelings today?	31	69	100	98.5	6.0
Overall, self-care self-efficacy	31	100	100	100	0
Quality of life	31	49	85	70	8.3

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Among his most frequently experienced symptoms included the following: frequency at night, unable to sleep, tiredness and pain.

Table 12 Mr D: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed. .

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	31	0	2	0.6	0.3
Blood in the urine	31	0	0	0	0
Diarrhoea	31	0	24	0.7	4.3
Impotence	31	0	48	2.9	11.4
Nausea	31	0	0	0	0
Pain	31	0	50	13.3	10.6
Tiredness	31	7	57	24.9	14.7
Unable to sleep	31	10	54	23.3	12.2
Urgency to pass urine	31	0	0	0	0
Urinate frequently during the day	31	0	28	3.6	7.8
Urinate frequently at night	31	52	100	70.3	14.2
Vomiting	31	0	0	0	0

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom

Four incident entries were completed see table 13. The incident entries were related to Mr D's self-management for his post-operative wound complications.

Table 13 Mr D: Incident entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Incident entry variables	N	Minimum	Maximum	Mean	SD
Positive coping	4	100	100	100	0
Negative coping	4	9	25.5	16.5	7.4
Negative affect	4	0	12.2	4.5	5.5
Positive affect	4	22.3	61.3	43.4	20.1
Tiredness	4	0	75	34.7	33.1
Received social support	4	47	100	85.5	25.7
Perceived social support	4	50	100	83.3	23.6

Incident entry date and time:	**Sought support**	**Description of the incident**
04.02.2011 14:36	Yes	Started having pain in the lower abdomen region. A drain had been taken out 4 days ago and the wound appeared to be healing ok but when showering it opened up and yellow pus oozed out.
04.02.2011 17:07	Yes	Unable to complete diary at 4pm because I was trying to stem the flow of yellowish pus from drain wound in stomach area.
09.02.2011 10:25	Yes	Wound still oozing pus and small amount of blood. Contacted district nurse who suggested I go to the treatment room at local medical centre to get wound dressed with more suitable dressings than I have been able to buy at chemist.
23.02.2011 16:13	Yes	Just above the drain wound, a small, slightly risen, bright red patch has appeared. It looks as if it could be a local infection in that area. Have made an appointment to see my GP tomorrow.

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

The results of the bivariate correlations analysis for Mr D are presented in table 14.

Table 14 Pearson's product moment correlation between all the variables for Mr D

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1) Positive coping	1														
2) Negative coping	0 .036	1													
3) Negative coping $_{\text{PreW lag 2}}$	0.028	0.835**	1												
4) SQRT Negative coping $_{\text{PreW lag 2}}$	0.022	0.827**	0.970**	1											
5) Negative affect	0.026	0.202*	0.132	0.139	1										
6) Negative affect $_{\text{PreW lag 1}}$	0.020	0.192	0.120	0.124	0.968**	1									
7) Positive affect	-0.057	0.215*	0.254*	0.229*	-0.307**	-0.307**	1								
8) Positive affect PreW lag 3	-0.034	0.000	0.040	0.021	-0.409**	-0.442**	0.780**	1							
9) Received social support	0 .005	0.329**	0.226*	0.218*	0.241*	0.168	-0.054	-0.164	1						
10) Received social support $_{\text{preW lag 1}}$	-0.002	0.304**	0.176	0.176	0.243*	0.183	-0.049	-0.197	0.974**	1					
11) Perceived social support	0.054	0.473**	0.166	0.188	0.103	0.089	0.054	-0.100	0.485**	0.548**	1				
12) Perceived social support $_{\text{preW lag 1}}$	0 .025	0.222*	0.045	0.083	0.112	0.073	-0.013	-0.187	0.555**	0.596**	0.826**	1			
13) Self-efficacy	0.176	0.051	0.115	0.159	0.039	0.027	0.077	0.015	0.054	0.046	-0.075	-0.029	1		
14) Demand	0.033	0.228	0.127	0.134	0.743**	0.746**	-0.408**	-0.447**	0.131	0.105	0.150	0.119	0.050	1	
15) Control	-0.014	-0.238*	-0.195	-0.198	-0.847**	-0.884**	0.258*	0.489**	-0.292**	-0.314**	-0.148	-0.209*	-0.021	-0.720**	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr E

Mr E was 65 year old married gentleman treated with neoadjuvant hormone therapy and radiotherapy for his locally advanced prostate cancer. A significant autocorrelation was found for positive coping (at a lag of 4) and positive affect and perceived social support (both at a lag of 1). No other variables in the data series displayed autocorrelation. The pre-whitening procedure was successfully applied to these variables. Negative coping displayed positive skewness and kurtosis and the Kolmogorov-Smirnov test was significant, D (94) = 0.510, $p<0.001$. A square root transformation was applied to negative coping and this reduced the impact of outliners and achieved normality.

Descriptive statistics of study variables – Mr E

Perceived social support and received social support were low (see table 15); with overall reduced satisfaction with his support (see table 16). Mr E reported good quality of life and experienced a number of symptoms (see table 17).

Table 15 Mr E: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-care demand	94	0	0	0	0
Self-care control	94	0	100	95.7	20.2
Positive coping	94	99	100	99.9	0.2
Negative coping	94	14.7	54.3	30	5.8
Negative affect	94	0	0.2	0.0	0.0
Positive affect	94	50	95	75.4	7.5
Self-care self-efficacy	94	90	100	99.9	1
Received social support	94	24	35	25.1	1.2
Perceived social support	94	24.5	99.8	24.8	11.2

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 16 Mr E: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	32	25	61	53.7	10.5
Were you able to discuss your thoughts and feelings today?	32	99	100	99.9	0.2
Did you want to discuss your feelings today?	32	0	100	88.3	27.3
Overall, self-care self-efficacy	32	99.5	100	99.9	0.2
Quality of life	32	91	100	99.2	2.3

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

The most frequently experienced symptoms included the following: impotence, urinary frequency and urinary urgency. Data suggests that bowel complaints were not problematic for Mr E.

Table 17 Mr E: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed. All scales are from 0-100.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	32	0	0	0	0
Blood in the urine	32	0	0	0	0
Diarrhoea	32	0	27	0.84	4.7
Impotence	32	99	100	99.9	0.1
Nausea	32	0	0	0	0
Pain	32	0	7	0.2	1.2
Tiredness	32	0	29	8.3	9.6
Unable to sleep	32	0	9	0.5	1.9
Urgency to pass urine	32	0	79	13.3	20.8
Urinate frequently during the day	32	0	86	17.4	21.5
Urinate frequently at night	32	0	89	14.3	20.7
Vomiting	32	0	0	0	0

A correlation analysis was undertaken between all the variables (including unaltered and altered variables). The results of the analysis can be seen in table 18 for Mr E.

Table 18 Pearson product moment correlations between all variables for Mr E.

	1	2	3	4	5	6	7	8	9	10	11	12	13
1) Positive coping	1												
2) Positive coping $_{\text{preW lag 4}}$	0.869**	1											
3) Negative coping	0.173	-0.129	1										
4) SQRT negative coping	0.229*	-0.146	0.993**	1									
5) Negative affect	0.025	-	0.129	0.136	1								
6) Positive affect	-0.031	-0.054	-0.028	-0.022	0.092	1							
7) Positive affect $_{\text{preW lag 1}}$	-0.072	-0.110	-0.072	-0.058	-	0.950**	1						
8) Self-efficacy	-0.031	-0.010	-0.003	-0.009	0.013	-0.004	-0.053	1					
9) Received social support	0.076	0.042	0.017	0.027	0.440**	0.060	0.003	0.010	1				
10) Perceived social support	-0.334**	-0.158	-0.038	-0.070	0.670**	0.062	0.033	-0.433**	0.269**	1			
11) Perceived social support $_{\text{preW lag 1}}$	-0.261*	-0.143	-0.035	-0.054	-	0.046	0.102	-0.735**	-0.035	0.843	1		
12) Demand	-	-	-	-	-	-	-	-	-	-	-	1	
13) Control	-0.050	-0.016	0.054	0.049	0.022	0.231*	0.208*	-0.027	0.014	0.028	0.010	-	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr F

Mr F was a 57 year old married gentleman, treated for his locally advanced prostate cancer with neoadjuvant hormone therapy and radiotherapy. A significant autocorrelation was found for received social support (at lag 6) and the pre-whitening procedure successfully removed the autocorrelation. No other variables in the data series displayed autocorrelation. Negative affect displayed positive skewness and the K-S test was significant, $D(78) = 0.210$, $p<0.001$. A logarithmic transformation was applied successfully to negative affect and achieved normalisation of this variable. Negative coping displayed positive skewness and kurtosis, and the Kolmogorov-Smirnov test was significant, $D(78) = 0.205$, $p<0.001$. A logarithmic transformation was applied successfully to negative coping and achieved normality in distribution.

Descriptive statistics of study variables – Mr F

Mr F reported high perceived social support and low received social support (see table 19), but with overall satisfaction with his support (see table 20). He also reported good quality of life (see table 20).

Table 19 Mr F: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-care demand	84	0	12	3.1	2.2
Self-care control	84	6	100	97.7	14.0
Positive coping	84	3	100	98.8	10.5
Negative coping	84	1	49	13.1	6.5
Negative affect	84	2	75	11.2	11.2
Positive affect	84	39	100	85.5	15.5
Self-care self-efficacy	84	98	100	99.9	0.2
Received social support	84	0	100	15.1	31.7
Perceived social support	84	97.0	100	99.9	0.4

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 20 Mr F: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed. All scales are from 0-100.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	25	26	100	93.3	20.2
Were you able to discuss your thoughts and feelings today?	25	91	100	99.6	1.8
Did you want to discuss your feelings today?	25	3	100	67.2	35.1
Overall, self-care self-efficacy	25	100	100	100	0
Quality of life	25	86	100	96.6	4.6

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

The most frequently experienced symptoms included the following: impotency, tiredness, unable to sleep, urinary frequency and urinary urgency (see table 22). Data suggests that bowel complaints were seldom experienced.

Table 22 Mr F: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	25	0	35	3.92	6.8
Blood in the urine	25	1	5	2.6	1.2
Diarrhoea	25	0	31	6.3	8.0
Impotence	25	76	100	98.2	5.5
Nausea	25	0	6	2.4	1.4
Pain	25	2	6	3.5	1.1
Tiredness	25	11	78	28.4	17.6
Unable to sleep	25	9	58	21.40	12.2
Urgency to pass urine	25	7	50	21.5	11.1
Urinate frequently during the day	25	4	31	14.9	7.0
Urinate frequently at night	25	7	57	21.0	12.5
Vomiting	25	1	6	3.2	0.9

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom

Mr F did not complete any incident reports. The results of Mr F's correlations are presented in table 23.

Table 23 Pearson product moment correlations between all variables for Mr F.

	1	2	3	4	5	6	7	8	9	10	11
1) Received support $_{\text{Pre-W lag 6}}$	1										
2) Received support	0.949**	1									
3) Negative affect	-0.125	-0.111	1								
4) Negative affect $_{(log)}$	-0.155	-0.104	0.834**	1							
5) Negative coping	-0.151	-0.161	0.148	0.243*	1						
6) Negative coping $_{(log)}$	-0.145	-0.108	0.178	0.266*	0.872**	1					
7) Positive affect	0.028	0.037	-0.004	-0.048	0.108	0.141	1				
8) Self-efficacy	0.034	0.042	-0.006	-0.053	0.111	0.143	1.0**	1			
9) Demand	0.160	0.169	-0.015	-0.014	-0.072	-0.098	-0.043	-0.042	1		
10) Control	-0.349**	-0.201	0.058	0.052	0.240*	0.523**	-0.019	-0.018	-0.265*	1	
11) Perceived support	-0.473**	-0.403**	0.080	0.143	0.206	0.467**	-0.021	-0.021	0.025	0.447**	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr G

Mr G was a 64 year old married gentleman, diagnosed with locally advanced prostate cancer and treated with neoadjuvant hormone therapy and radiotherapy. Mr G also had pre-existing health problems and these included: asthma, hypertension and depression. A number of significant autocorrelations were found at a lag of 1 for the following variables: positive coping, negative coping, negative affect and received social support. Positive affect displayed autocorrelation at a lag of 3, and self-management control at a lag of 4. Pre-whitening procedure was applied to each of these variables, and removed the autocorrelation. Negative affect $_{(\text{pre-w lag } 1)}$ displayed kurtosis and skewness $p<0.001$, the K-S statistic was also significant $D(95)=0.170$, $p<0.001$. A square root transformation (and a constant of 21 [the largest of the negative values was -20.74]) achieved normality in distribution. Pre-whitened received social support had a number of outliners visible from the SPSS box plot, and the K-S $D(95)=0.284$, $p<0.001$, kurtosis $p<0.001$. A square root transformation (+ constant of 6 [lowest value -5.9]) improved the normality distribution and reduced the impact of the outliners.

Descriptive statistics for Mr G

Mr G reported little received social support and reduced perceived social support scores (see table 24). Mr G was highly dissatisfied with his social support (table 25). His quality of life was reduced and he experienced a number of symptoms (see table 25 and 26)..

Table 24 Mr G: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Positive coping	96	32	93	58	11.3
Negative coping	96	26.3	63.3	39.8	5.2
Self-care demand	96	0	68	10.7	16.1
Self-care control	96	1	100	89.9	19.3
Negative affect	96	0	68.6	12.9	14.5
Positive affect	96	17	78	41.7	15.5
Self-care self-efficacy	96	1	100	93.9	10.2
Received social support	96	0	40.5	3	6.2
Perceived social support	96	33.7	79.75	43.5	4.5
Tired	96	0	93	60.9	24.6

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 25 Mr G: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	33	6.5	59	18.8	7.9
Were you able to discuss your thoughts and feelings today?	33	57	93	69.6	8.3
Did you want to discuss your feelings today?	33	29	95	62.6	14.7
Overall, self care self-efficacy	33	88	99	94.2	2.5
Quality of life	33	21	89	65.1	13.8

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

The most frequently experienced symptoms included: tiredness, unable to sleep, urinary frequency, urinary urgency and constipation (see table 26).

Table 26 Mr G: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	33	0	83	35.4	27.9
Blood in the urine	33	0	4	.88	1.1
Diarrhoea	33	0	5	1.39	1.2
Impotence	33	0	4	1.21	1.5
Nausea	33	0	23	2.36	4.1
Pain	33	0	46	4.64	10.2
Tiredness	33	3	94	63.8	19.3
Unable to sleep	33	1	91	43.2	24.9
Urgency to pass urine	33	0	79	10.9	19.7
Urinate frequently during the day	33	2	83	47.2	25.7
Urinate frequently at night	33	0	71	28.5	29.1
Vomiting	33	0	5	1.79	1.5

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom

Three incident entries were completed and these related to bowel self-management, table 27. Mr G reported a composite of positive and negative coping styles and high perceived social support, although he did not seek social support to help with his incident experience.

Table 27 Mr G: Incident entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Incident entry variables	N	Minimum	Maximum	Mean	SD
Positive coping	3	56	91	74.7	17.6
Negative coping	3	28.5	37	33.5	4.4
Negative affect	3	5	18.4	12.8	6.9
Positive affect	3	27	53.3	43	14.1
Received social support	3	0	2	1	1
Perceived social support	3	94	100	96.3	3.2

Incident entry date and time:	**Sought support**	**Description of the incident**
18.11.2010 16:07.	No	1) Sudden need to have a bowel movement.
01.12.2010 10:05.	No	2) Had to rush to the toilet to empty bowels and was late for diary entry.
17.12.2010 11:19	No	3) Accidentally defecated into my underpants.

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

A bivariate correlation analysis was undertaken between all the variables (including unaltered and altered variables), see table 28.

Table 28 Pearson product moment correlations between all variables for Mr G

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1) Positive coping	1																
2)Positive coping (PreW lag1)	0.836*	1															
3) Negative coping	-0.110	-0.217*	1														
4) Negative coping (PreW lag 1)	-0.125	-0.110	0.924**	1													
5) Positive affect	0.228*	0.144	0.007	-0.075	1												
6) Positive affect (preW lag 3)	0.058	0.075	- 0.101	-0.115	0.938**	1											
7) Negative affect	0.259*	0.108	0.411**	0.240*	0.144	-0.014	1										
8) Negative affect (preW lag 1)	0.116	0.092	0.278**	0.224*	0.064	-0.015	0.926**	1									
9) SQRT Negative affect$_{(preW\ lag\ 1)}$	0 .088	0.069	0.243*	0.197	0.078	0.001	0.870**	0.971**	1								
10) Received social support	0 .372**	0.175	0.175	0.006	0.228*	0.063	0.259*	0.080	0.080	1							
11) Received social support$_{(preW\ lag\ 1)}$	0.186	0.183	0.034	0.052	0.102	0.071	0.117	0.135	0.145	0.959**	1						
12) SQRT Received social support$_{(preW\ lag1)}$	0.180	0.180	0.069	0.083	0.100	0.072	0.134	0.145	0.159	0.894**	0.969**	1					
13) Perceived social support	-0.096	-0.158	0.245*	0.172	0.016	0.031	0.061	0.051	0.039	0.188	0.007	0 .001	1				
14) Self-care demand	0.031	-0.012	-0.008	-0.049	-0.084	-0.102	-0.060	-0.054	-0.067	0.054	-0.007	-0.061	0.029	1			
15) Self-care control	0.059	0.066	0.024	0.045	0.035	0.085	-0.030	-0.034	-0.061	0.033	0.022	0.056	0.067	-0.191	1		
16) Self-care control$_{(preW\ lag4)}$	0.071	0.060	-0.006	0.008	0.063	0.063	0.032	0.046	0.016	0.095	0.087	0.093	-0.021	-0.097	0.947**	1	
17) Self-care self-efficacy	0.008	0.037	0.047	0.140	0.129	0.110	-0.075	-0.046	-0.057	0.027	0.049	0.028	-0.047	0.122	-0.056	-0.039	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr H

Mr H was a 73 year gentleman who was divorced with no partner. He was diagnosed with locally advanced prostate cancer and treated with neoadjuvant hormone therapy and radiotherapy. A significant autocorrelation was found for negative affect, received and perceived social support (at a lag 1). The pre-whitening procedure was applied and effectively removed the presence of autocorrelation. No other variables in the data series displayed autocorrelation. A log transformation was successfully applied to self-management demand. Several transformations (Tabachnick and Fidell, 2004) were applied self-efficacy, self-management control and negative coping however; were unsuccessful, and so these variables were left untransformed.

Descriptive statistics of study variables – Mr H

Mr H reported little received social support and moderate perceived social support (see table 29). He also experienced a moderate degree of negative affect and a composite of positive and negative coping styles. Mr H was dissatisfied with his social support and experienced a reduced quality of life (see table 30) and experienced variety of symptoms (see table 31).

Table 29 Mr H: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-care demand	91	4	69	18.6	11.5
Self-care control	91	10	99	84.1	17.4
Positive coping	91	65	100	90.2	6.5
Negative coping	91	5.2	53.3	29.8	10.5
Negative affect	91	8.6	80.8	39.9	15.5
Positive affect	91	7	77.7	49.1	12.6
Self-care self-efficacy	91	51	98.5	90.5	5.7
Received social support	91	2.5	73	22.5	12.1
Perceived social support	91	3.5	93.5	46.7	20.7

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 30 Mr H: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	32	21	98	53.6	19.1
Did you want to discuss your feelings today?	32	9	96	29.4	23.3
Were you able to discuss your thoughts and feelings today?	32	10	100	28.8	32.1
Overall, self-care self-efficacy	32	54.5	98.5	91.5	7.7
Quality of life	32	13	99	57.6	20.9

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Mr H experienced a number of symptoms (see table 31) including: constipation, diarrhoea, impotence, nausea, pain, tiredness and unable to sleep, urinary frequency and urgency.

Table 31 Mr H: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	32	15	91	49.5	18.5
Blood in the urine	32	6	71	15.3	13.5
Diarrhoea	32	5	93	31.6	22.8
Impotence	32	67	100	91.3	6.1
Nausea	32	6	66	23.8	16.9
Pain	32	11	98	44.8	33.1
Tiredness	32	25	95	72.4	16.9
Unable to sleep	32	11	95	64.1	25.4
Urgency to pass urine	32	11	98	84.5	19.1
Urinate frequently during the day	32	79	100	91.3	5.1
Urinate frequently at night	32	61	96	88.9	6.7
Vomiting	32	1	22	12.5	4.2

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom

Mr H did not complete any incident entries throughout the course of his data collection. A correlation analysis was undertaken between all the variables (including unaltered and altered variables) and the results of the analysis are displayed in table 32.

Table 32 Pearson product moment correlations between all variables for Mr H.

	1	2	3	4	5	6	7	8	9	10	11	12	13
1) Positive coping	1												
2) Negative coping	-0.089	1											
3) Positive affect	0.194	-0.290**	1										
4) Negative affect	-0.258*	0.357**	-0.577**	1									
5) Negative affect$_{(PreW\ lag\ 1)}$	-0.278**	0.331**	-0.468**	0.888**	1								
6) Demand	-0.296**	0.161	-0.244*	0.310**	0.351**	1							
7) Demand log	-0.356**	0.188	-0.266*	0.339**	0.359**	0.920**	1						
8) Control	-0.055	-0.121	0.174	-0.286**	-0.240*	-0.122	-0.066	1					
9) Received social support	0.092	0.109	0.074	0.234*	0.210*	0.018	0.098	-0.029	1				
10) Received social support$_{(PreW\ lag\ 1)}$	-0.008	0.179	-0.065	0.299**	0.184	0.027	0.124	-0.026	0.915**	1			
11) Perceived social support	0.283**	-0.261*	0.387**	-0.412**	-0.272**	-0.210*	-0.221*	0.078	0.205	0.102	1		
12) Perceived social support$_{(PreW\ lag\ 1)}$	0.266*	-0.197	0.252*	-0.299**	-0.266*	-0.240*	-0.198	0.038	0.160	0.198	0.881**	1	
13) Self-efficacy	0.223*	-0.020	0.073	0.040	-0.018	-0.038	-0.040	-0.032	0.145	0.071	0.123	0.170	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr I

Mr I is a 73 year old single gentleman who was also treated for his locally advanced prostate cancer treated by neoadjuvant hormone therapy and radiotherapy. Mr I had pre-existing health problems and these included asthma and hypertension.

Preliminary analysis– Mr I

Autocorrelation was present for positive coping, positive affect, received social support and perceived social support (at a lag of 2), and for negative coping and self-care demand (at a lag of 1). These variables underwent the pre-whitening procedure and successfully removed the autocorrelation. Self-care demand $_{(PreW\ lag\ 1)}$ was negatively skewed and the K-S was significant (75)=0.120, P=0.009. A square root transformation (and a constant + 30 [lowest negative value -29.7]) achieved normality of self-care demand $_{(PreW\ lag\ 1)}$. Self-care control was negatively skewed and displayed positive kurtosis, and the K-M was significant (76)=0.130, P=0.003. Transformation (Tabachnick and Fidell, 2004) were applied and were unsuccessful in improving normality and reducing the impact of outliners (case number 11 [value 55] and case number 16 [value 52]). The values of the two univariate outliners were replaced with one unit smaller than the next extreme value in the distribution (Tabachnick and Fidell, 2004) (case number 11 value was replaced with 51) and (case number 11 value was replaced with 50). This was successful in improving the assumptions for this variable K-S (76)= 0.086, P=0.200. Negative affect displayed positive kurtosis and the K-S was significant (76)=0.110, P=0.024. A SQRT transformation was applied to negative affect and was successful in reducing the kurtosis, K-S (76)=0.083, P=0.200. Received social support $_{(PreW\ lag\ 2)}$ was positively skewed and kutotic, the K-S was significant (74)=0.120,P=0.010. A square root transformation and constant of 11 (lowest negative value for this variable was -10.4) achieved normality in distribution for received social support $_{(PreW\ lag\ 2)}$, K-M (74)=0.080, P=0.200. Perceived social support $_{(PreW\ lag\ 2)}$ displayed positive kurtosis, a square root transformation (+ constant of 8, lowest negative value was -7.07) achieved normality K-S (74)=0.060, P=0.200.

Descriptive statistics of study variables

Mr I received little social support and had low perceived social support (see table 33); and was highly dissatisfied with his support (see table 34). Mr I reported reduced quality of life and he experienced a number of symptoms (see table 34 and 35).

Table 33 Mr I: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

	N	Minimum	Maximum	Mean	SD
Self-care demand	76	0	70	28.8	13.7
Self-care control	76	66	98	82.8	6.8
Positive coping	76	50	94	71.7	8.8
Negative coping	76	4	16.5	7.5	2.1
Negative affect	76	6	36.8	17.9	4.9
Positive affect	76	11	71.3	42.1	15.6
Self-care self-efficacy	76	74.5	94.5	82.8	3.6
Received social support	76	0.7	41.5	12.5	6.7
Perceived social support	76	15.7	40	24.3	4.8

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 34 Mr I: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	30	15	39.7	26.8	6.8
Did you want to discuss your feelings today?	30	44	98	80.1	12.3
Were you able to discuss your thoughts and feelings today?	30	20	99	64.8	22.7
Overall, self-care self-efficacy	30	70	90	81.1	4.5
Quality of life	30	19	69	46.9	12.5

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Mr I experienced a number of symptoms (see table 42) these included: constipation, impotence, pain, tiredness and unable to sleep, and urinary frequency and urgency.

Table 35 Mr I: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	30	0	78	13.8	20.9
Blood in the urine	30	0	56	8.6	14.8
Diarrhoea	30	0	3	0.9	0.9
Impotence	30	82	100	95.2	5.3
Nausea	30	0	3	1.3	.9
Pain	30	13	54	23.6	8.1
Tiredness	30	20	78	55.1	14.3
Unable to sleep	30	20	84	58.1	17
Urgency to pass urine	30	2	100	90.3	24.2
Urinate frequently during the day	30	41	88	64.7	11.2
Urinate frequently at night	30	51	97	74.8	13.2
Vomiting	30	0	3	1.3	0.9

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom.

Mr I did not report any incident reports throughout his data collection. Bivariate correlation coefficients for Mr I are displayed in table 36.

Table 36 Pearson product moment correlations between all variables for Mr I.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
1) Positive coping	1																		
2) Positive coping$_{(PreW\ lag\ 2)}$	0.884**	1																	
3) Negative coping	0.171	0.233*	1																
4) Negative coping$_{(PreW\ lag\ 1)}$	0.093	0.191	0.954**	1															
5) Demand	-0.382**	-0.318**	-0.174	-0.151	1														
6) Demand $_{(PreW\ lag\ 1)}$	-0.261	-0.257*	-0.081	-0.111	0.929**	1													
7) SQRT Demand $_{(PreW\ lag\ 1)}$	-0.199	-0.169	-0.029	-0.063	0.890**	0.972**	1												
8) Control	0.245*	0.191	0.065	-0.099	-0.264*	-0.198	-0.160	1											
9) Positive affect	0.169	0.099	-0.273*	-0.477**	-0.146	-0.126	-0.161	0.239*	1										
10) Positive affect $_{(PreW\ lag\ 2)}$	0.216	0.168	-0.348**	-0.397**	-0.180	-0.209	-0.251*	0.187	0.944**	1									
11) Negative affect	-0.026	0.025	0.085	0.172	-0.037	-0.094	-0.136	0.176	0.077	0.112	1								
12) SQRT negative affect	-0.015	0.061	0.121	0.216	-0.063	-0.116	-0.149	0.147	0.048	0.093	0.992**	1							
13) Self-efficacy	0.093	0.064	-0.254*	-0.133	-0.091	-0.133	-0.134	0.292*	0.092	0.086	-0.024	-0.088	1						
14) Received social support	-0.217	0.124	-0.231*	-0.206	0.030	-0.027	-0.019	-0.027	0.096	0.137	-0.058	-0.038	-0.088	1					
15) Received social support $_{(PreW\ lag\ 2)}$	-0.151	-0.115	-0.227	-0.198	0.047	-0.007	-0.006	0.017	0.068	0.117	-0.074	-0.063	-0.075	0.950**	1				
16) SQRT received social support$_{(Prew\ lag\ 2)}$	-0.136	0.099	-0.179	-0.145	0.065	0.032	-0.029	-0.013	0.047	0.092	-0.140	-0.124	-0.137	0.910**	0.972**	1			
17) Perceived social support	-0.190	-0.172	-0.081	-0.297**	0.090	0.134	0.109	0.013	0.169	0.136	-0.185	-0.216	0.159	0.546**	0.542**	0.517**	1		
18) Perceived social support$_{(PreW\ lag\ 2)}$	-0.058	0.021	-0.169	-0.136	0.065	0.080	0.087	-0.130	0.072	0.124	-0.196	-0.196	0.103	0.554**	0.546**	0.557**	0.879**	1	
19) SQRT Perceived social support$_{(PreW\ lag\ 2)}$	-0.041	0.029	-0.133	-0.103	0.088	0.109	0.115	-0.141	0.027	0.085	-0.195	-0.192	0.083	0.551**	0.558**	0.584**	0.850**	0.982*	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr J

Mr J was a 73 year old, married gentleman, who was diagnosed with metastatic prostate cancer. He was being treated with hormone therapy. Significant autocorrelations were found at a lag of 1 for positive coping, negative coping, self-efficacy, received social support, and for demand (at a lag of 2) and control (at a lag of 3). The pre-whitening procedure was applied and was successful in removing the presence of autocorrelation. Positive coping $_{(PreW\ lag\ 1)}$, negative affect $_{(PreW\ lag\ 1)}$, self-efficacy $_{(PreW\ lag\ 1)}$, perceived social support, demand $_{(PreW\ lag\ 2)}$ and control $_{(PreW\ lag\ 3)}$ displayed normality and the results of the K-S were non-significant. Negative coping $_{(PreW\ lag\ 1)}$ displayed positive skewness $P<0.001$, and the K-S (87) = 0.249, $P<0.01$. A square root transformation (and a constant of + 10 [lowest negative value -9.5]) was successful in reducing the skewness and achieved normality of negative coping $_{(PreW\ lag\ 1)}$.

Descriptive statistics of study variables – Mr J

Mr J reported moderate social support with reduced perceived social support (see table 37); but had overall satisfaction (see table 38). He reported reduced quality of life and experienced number symptoms (see table 39).

Table 37 Mr J: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-care demand	88	2	12	7.1	2.1
Self-care control	88	57	93	76.2	5.5
Positive coping	88	66	89	75.4	4.5
Negative coping	88	3.5	25.4	8.1	4.3
Negative affect	88	3.4	9.4	6.3	1.4
Positive affect	88	57	78.7	71.5	4.5
Self-care self-efficacy	88	60.5	91.5	75.6	4.4
Received social support	88	7.5	78.5	65.4	11.9
Perceived social support	88	46.5	85.7	69.5	5.5

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 38 Mr J: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	28	60.5	86.75	67.5	5.3
Were you able to discuss your thoughts and feelings today?	28	25	81	65.3	10.6
Did you want to discuss your feelings today?	28	3	68	13	11.9
Overall, self care self-efficacy	28	68	85.5	75.5	4.1
Quality of life	28	61	90	72.1	6.5

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Impotence and urinary urgency and urinary frequency were experienced by Mr J, see table 39.

Table 39 Mr J: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	28	2	10	5.7	1.9
Blood in the urine	28	2	11	6.1	2.2
Diarrhoea	28	3	29	8.2	5.9
Impotence	28	61	88	70.8	5.7
Nausea	28	2	8	5.7	1.7
Pain	28	4	9	6.6	1.4
Tiredness	28	1	22	7.9	5.3
Unable to sleep	28	2	17	8.1	3.4
Urgency to pass urine	28	6	79	57.5	14.1
Urinate frequently during the day	28	45	77	61.5	7.7
Urinate frequently at night	28	46	76	62.3	7.2
Vomiting	28	3	11	6.7	1.8

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom.

Mr J did not complete any incident entries and the results of the correlation analysis (including unaltered and altered variables) are displayed in table 40.

Table 40 Pearson product moment correlations between all variables for Mr J.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1) Positive coping	1																
2) Positive coping (PreW lag 1)	0.892**	1															
3) Negative coping	0.462**	0.272*	1														
4) Negative coping (PreW lag 1)	0.127	0.108	0.824**	1													
5) SQRT negative coping (PreW lag 1)	0.034	0.040	0.695**	0.961**	1												
6) Negative affect	0.389*	0.281**	0.427**	0.239*	0.198	1											
7) Negative affect (PreW lag 1)	0.302**	0.297**	0.249*	0.175	0.161	0.908**	1										
8) Positive affect	-0.007	0.118	-0.101	0.087	0.096	-0.216**	-0.067	1									
9) Self-efficacy	0.541**	0.336**	0.528**	0.128	0.027	0.455**	0.296*	-0.037	1								
10) Self-efficacy (PreW lag 1)	0.259*	0.224*	0.253*	0.034	-0.031	0.259*	0.226*	0.095	0.773**	1							
11) Received social support	-0.426**	-0.199	-0.635**	-0.353**	-0.235*	-0.281**	-0.110	0.319**	-0.565**	-0.295**	1						
12) Received social support (PreW lag 1)	0.024	0.108	-0.222*	-0.211*	-0.127	-0.129	-0.052	0.353**	-0.099	-0.067	0.682**	1					
13) Perceived social support	0.003	0.061	-0.213*	-0.389**	-0.380**	0.005	0.072	0.075	-0.013	0.053	0.478**	0.470**	1				
14) Demand	0.159	0.094	0.245*	0.183	0.158	0.506**	0.430**	0.009	0.205	0.154	0.024	0.083	-0.015	1			
15) Demand (PreW lag 2)	0.239*	0.135	0.254*	0.175	0.138	0.479**	0.413**	-0.068	0.268*	0.218*	-0.057	0.006	0.009	0.949**	1		
16) Control	0.519**	0.301**	0.550**	0.225*	0.143	0.460**	0.298**	-0.126	0.770**	0.524**	-0.545**	-0.164	-0.093	0.151	0.180	1	
17) Control (PreW lag 3)	0.253*	0.197	0.249*	0.144	0.132	0.250*	0.187	0.092	0.456**	0.392**	-0.081	0.082	0.048	0.106	0.094	0.815**	1

*p<0.05, **p<0.01 (2-tailed)

Case report Mr K

Mr K was a 72 year old married gentleman who was diagnosed with metastatic prostate cancer and treated with hormone therapy. Significant autocorrelations were found at a lag of 1 for the following variables: negative affect, negative coping, positive affect, and self-care self-efficacy, received and perceived social support. Positive affect had a significant correlation at a lag of 3. The pre-whitening procedure effectively removed the presence of autocorrelation for these variables. Negative coping $_{(PreW\ lag\ of\ 1)}$ was positively skewed and kurtotic, P<0.001 and the K-S was significant (84)=0.352, P<0.001. A square root transformation (and a constant of + 5 [4.69 was the lowest value]) achieved normality in distribution for negative coping $_{(PreW\ lag\ of\ 1),}$ K-S (84) =0.071, P=0.200. Received social support $_{(PreW\ lag\ of\ 1)}$ displayed kurtosis, P<0.001, and a square root transformation (and constant of 7 [lowest value was -6.87]) was applied and achieved normality in distribution, K-S (84) = 0.069, P=0.200.

Descriptive statistics of study variables – Mr K

Mr K received little social support and scored moderately for perceived social support (see table 41); with reduced satisfaction with social support scores (see table 42). Mr K experienced a number of symptoms and these are displayed in table 43.

Table 41 Mr K: Standard entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Self-care demand	85	0	20	1.34	2.7
Self-care control	85	81	100	94.6	4.6
Positive coping	85	79	100	93.3	4.2
Negative coping	85	9.3	32.7	24.6	3.4
Negative affect	85	0	13.6	0.6	1.7
Positive affect	85	46.3	90.7	73.5	10.1
Self-care self-efficacy	85	85	100	94.2	3.4
Received social support	85	4.3	21.7	9.8	3.8
Perceived social support	85	32.3	97.7	77.8	9.3

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Table 42 Mr K: End of day entry: means, standard deviations, minimum and maximum values for psychological and social support variables, untransformed.

Standard entry variables	N	Minimum	Maximum	Mean	SD
Satisfaction with social support	29	56	89.7	67.7	8.9
Did you want to discuss your feelings today?	29	0	59	6.3	13.5
Were you able to discuss your thoughts and feelings today?	29	93	100	95.8	2.4
Overall, self-care self-efficacy	29	84	98.5	93.6	3.9
Quality of life	29	66	87	74	4.5

All scales are from 0-100. A higher number is interpreted as a higher score of that variable

Mr K experienced the following symptoms: urinary urgency and frequency, pain, tiredness and unable to sleep (see table 43).

Table 43 Mr K: Self-reports of symptoms enquired about at end of day entry. Means, standard deviations, minimum and maximum values, untransformed.

Daily ratings of symptom	N	Minimum	Maximum	Mean	SD
Constipation	29	0	9	0.6	1.7
Blood in the urine	29	0	7	0.4	1.4
Diarrhoea	29	0	52	3.4	11.7
Impotence	29	0	7	0.5	1.4
Nausea	29	0	7	0.6	1.6
Pain	29	16	39	27.4	5.4
Tiredness	29	11	29	21.9	4.7
Unable to sleep	29	0	26	17.7	6.6
Urgency to pass urine	29	20	85	36.6	14.1
Urinate frequently during the day	29	21	75	34.3	11.6
Urinate frequently at night	29	12	66	30.1	10.9
Vomiting	29	0	2	0.2	0.6

The ratings (0=not at all, 100=always). A higher score is interpreted as the higher frequency of the symptom.

Mr K did not complete any incident entries throughout the course of his data collection. The results of Mr K's bivariate correlation are displayed in table 44.

Table 44 Pearson product moment correlations between all variables for Mr K.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1) Positive affect	1																	
2) Positive affect (PreW lag 3)	0.704**	1																
3) Negative affect	0.164	0.217	1															
4) Negative affect (PreW lag 1)	0.172	0.138	0.660**	1														
5) Negative coping	-0.485**	-0.264*	-0.422**	-0.012	1													
6) Negative coping (PreW lag 1)	-0.339**	-0.313**	0.130	-0.190	0.744**	1												
7) SQRT negatve coping (PreW lag 1)	-0.328**	-0.280*	0.108	-0.141	0.764**	0.979**	1											
8) Positive coping	0.198	0.033	-0.019	0.163	0.232*	0.187	0.207	1										
9) Positive coping (PreW lag 1)	0.199	0.037	0.257*	0.093	0.112	0.223*	0.238*	0.944**	1									
10) Self-efficacy	0.151	0.098	0.048	0.153	0.152	0.196	0.213	0.450**	0.385**	1								
11) Self-efficacy (PreW lag 1)	0.096	0.080	0.242*	0.041	0.078	0.242*	0.253*	0.345**	0.350**	0.933**	1							
12) Received social support	-0.445**	-0.326**	-0.081	-0.182	0.402**	0.348**	0.348**	-0.110	-0.071	-0.055	-0.027	1						
13) Received social support (PreW lag 1)	-0.232*	-0.235*	0.038	-0.172	0.201	0.263**	0.255*	-0.156	-0.108	-0.037	0.001	0.800**	1					
14) SQRT received social support (PreW lag 1)	-0.237*	-0.214	0.018	-0.143	0.212	0.250*	0.247*	-0.146	-0.111	-0.027	0.009	0.740**	0.976**	1				
15) Perceived social support	-0.546**	0.150	0.430**	0.360**	-0.321**	-0.080	-0.085	0.203	0.251*	0.328*	0.294**	-0.239*	-0.080	-0.095	1			
16) Perceived social support (preW lag 1)	0.264*	-0.041	0.314**	0.223*	-0.130	0.016	-0.001	0.052	0.098	0.236*	0.237*	-0.044	0.078	0.062	0.813**	1		
17) Demand	-0.113	-0.081	0.288**	0.100	-0.044	0.113	0.052	-0.197	-0.210	-0.018	0.039	-0.123	-0.143	-0.124	0.014	-0.035	1	
18) Control	0.191	0.038	-0.033	0.135	0.122	0.124	0.113	0.488**	0.421**	0.462	0.326**	-0.105	-0.007	-0.007	0.238*	0.144	-0.013	1

*p<0.05, **p<0.01 (2-tailed)